EPA REGISTRATION NUMBER 35935-38 – VOL. 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 30 2014

Matthew Granahan
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803

Subject: Label Notification per PRN 98-10
Product Name: Dicamba Acid Technical
EPA Registration Number: 35935-38
Application Dated: April 17, 2014

Dear Mr. Granahan,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for Dicamba Acid Technical (EPA Reg. No. 35935-38) dated April 17, 2014. The Registration Division (RD) has conducted a review of this request and finds that the action requested will require additional administrative review of the related files. Below is a summary of our findings:

1. This action exceeds what can be done via notification because it will require data review. Therefore, it must be resubmitted under PRIA code R351.

Therefore, the RD has determined that this action is denied and our records have been updated accordingly. No further processing of this action will occur until a resubmission is made. If you have any questions, please contact Emily Schmid of my staff at (703) 347-0189 or schmid.emily@epa.gov.

Sincerely,

Emily Schmid for

Kathryn V. Montague, Product Manager 23
Herbicide Branch
Registration Division
Office of Pesticide Programs

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

Via Overnight Courier

April 17, 2014

Kathryn Montague (PM-23)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Formulation Notification per PRN 98-10

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a Formulation Notification per Pesticide Registration Notice 98-10 on Dicamba Acid Technical, EPA Reg No 35935-38. On this submission we have revised CSF Alternate #2 by correcting the Producer in Box 2 on CSF, from Nufarm Americas Inc. to [redacted] and replaced one optional repacking EPA facility with three optional repacking EPA facilities (please note the Supplier Name in Box 11 on CSF has not changed, but we have corrected the address of the supplier on Box 11 on CSF).

Nufarm wishes to have the submitted CSF Alternate 2 replace the CSF Alternate 2 on file with the Agency. Nufarm wishes to have the Basic CSF accepted by the Agency remain unchanged (CSF Alt 1 and Alt 3 are currently pending – PRIA dates of 05/05/2014 and 07/15/2014, respectively).

This submission is thought to fall in line with PR Notice 98-10 Section III (Product Chemistry Notifications); as such no PRIA fee has been rendered.

To process this request please find enclosed the following:

- Application for Pesticide Registration EPA Form 8570-1
- Revised Alternate #2 CSF (2 Copies)
- Formulator's Exemption EPA Form 8570-27

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

Product ingredient source information may be entitled to confidential treatment

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathryn Montague	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Formulation notification consistent and 98-10, see cover letter for detailed explanation. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	50 - 250 lbs, bulk	[X]

6. Manner in Which Label is Affixed to Product [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other Self-Adhesive Integrated Label/Booklet

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Granahan	Regulatory Manager	(708) 377-1821

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Regulatory Manager	Matthew Granahan matthew.granahan@us.nufarm.com	04/17/2014

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	35935-38
	Product Name Dicamba Acid Technical
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 08/06/09, 08/13/13(pending), 04/17/14(pending), 04/17/14 (submitted)

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Dicamba (3,6-dichloro-o-anisic acid)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Dicamba (3,6-dichloro-o-anisic acid)	[redacted]	[redacted]

Product ingredient source information may be entitled to confidential treatment

Signature	Name and Title	Date
	Matthew Granahan Regulatory Manager	04/17/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Material Sent for Data Extraction

Reg # 35935-38

Description: _____

Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☐ Notification Dated _____
- ☒ New CSF(s) Dated 10-17-13 AH#3
- ☐ Other: _____

Decision #: _____

Other Action/Comments: _____

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Kathryn Montague

Phone: (703)305-0123 Division: RD/PM Team 23

Date: 9-7-14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Matthew Granahan
Nufarm Limited
4020 Aerial Center Pkwy., Suite 101
Morrisville, NC 27560

JUL - 7 2014

Subject: Alternate # 3 Confidential Statement of Formula (CSF)
Adding New Source of Active Ingredient
EPA Reg. No.: 35935-38
Dicamba Acid Technical
Submission Dated October 17, 2013

Dear Mr. Granahan,

The Agency has received your request to amend the registration described above by adding an alternate formulation, containing a new, unregistered source of the active ingredient. The new CSF, alternate #3, dated October 17, 2013, is acceptable, and has been added to the file for your product. A copy of the chemistry review is attached.

If you have any questions, please contact Kathryn Montague (703-305-1243 or montague.kathryn@epa.gov).

Sincerely,

Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

FEE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP Barcode No.: D418778 File Symbol No.: 35935-38 Decision No.: 484122
PC Code: 029801 Action Code: R 351
Food Use: No Product Name: Dicamba Acid Technical

Date: June 16, 2014

SUBJECT: Product Chemistry Review of Dicamba Acid Technical

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch/RD (7505P)
Registration Division (7505P)

Bruce F. Kitchens
16 June 2014

TO: RM #23, Kathryn V. Montague
Herbicide Branch
Registration Division (7505P)

SBM 6/17/14

INTRODUCTION:

The registrant, Nufarm Limited, is submitting an application to amend the registered manufacturing use product, Dicamba Acid Technical. This amendment is the result of the addition of an alternate source of the active ingredient. The active ingredient in this product is Dicamba at a label nominal concentration of 98% a.i. This product is intended for use in the manufacture of herbicide end-use products. In support of this request, the registrant has submitted an alternate (alt. #3) Confidential Statement of Formula (CSF) dated 17 Oct 2013 and product chemistry data contained in MRID#s 492264-01, -02, -03, -04, -05, and 492585-01 . The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.

2. All impurities have been assayed and identified by the registrant. The registrant has not declared any impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits.

3. The nominal concentration of the active ingredient listed on the proposed alternate CSF (97.87%) and the current basic CSF (98.0%) are not the same. The active ingredient nominal concentration listed on the proposed alternate formula does fall within the active ingredient certified limits listed on the current basic CSF and is acceptable.

4. The active ingredient's certified limits as proposed on the alternate CSF are acceptable.

5. The alternate production is:

[redacted]

Optional Repacking:

[redacted]

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The proposed alternate formula CSF for the manufacturing use product, Dicamba Acid Technical dated 17 Oct 2013 is acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.

   Inform the registrant that data for physical and chemical properties are not required for a proposed alternate formula for a technical product.

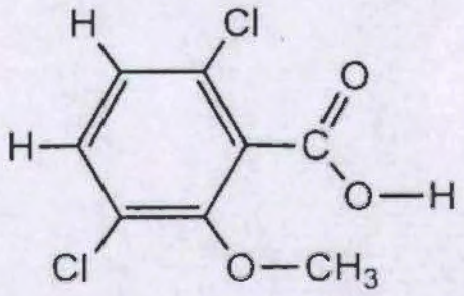
3. The proposed alternate formula for Dicamba Acid Technical meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.

Product ingredient source information may be entitled to confidential treatment

DP Barcode No.: D418778 File Symbol No.: 35935-38 Decision No.: 484122
PC Code: 029801 Action Code: R 351
Food Use: No Product Name: Dicamba Acid Technical

830.1550. Product Identity & Composition:

Common Name:	Dicamba Acid
Chemical Name (CAS):	3,6-dichloro-2-methoxybenzoic acid
(IUPAC):	3,6-dichloro-o-anisic acid
CAS No.:	1918-00-9
PC Code No.:	029801
Empirical formula:	$C_8H_6Cl_2O_3$
Molecular Weight:	221.04
Nominal Concentration:	98.0% a.i.
Structural formula:	



DICAMBA ACID

Table 1. Manufacturing and Impurity Data for Dicamba Acid Technical

GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and Composition	492264-01	A	The NC of AI (97.87%) is supported by 5 batch analysis & agrees with the label claim NC, [redacted] are listed on the CSF.
8301600	Description of Materials Used to Produce the Product	492264-01	A	The product specification sheets (MSDS) for all the starting materials have been provided by the registrant
830.1620	Description of Production Process	492264-01	A	The AI was produced in a three step integrated process. The production process has been described in full details. The reaction conditions, amounts of chemicals in each step, duration of time, and the yields in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of Formation of Impurities	492264-01 492585-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present at the levels of ≥ 0.1%. [redacted] have been listed on the CSF. No toxic impurities were reported during the synthesis.
830.1700	Preliminary Analysis	492264-02	A	The registrant has provided 5 batch analysis for the TGAI. The AI & impurities were identified and quantified by HPLC/UV with external calibration method. The AI and impurities methods were validated. The LOQ and LOD for the AI & each impurity have been determined. The five batch analysis supported the CSF for the proposed alternate formulation.
830.1750	Certified Limits	492264-01	A	The proposed certified limits for the AI & for the impurities are based on the five batch analytical results.
830.1800	Enforcement Analytical Method	492264-01 492264-02	A	An HPLC/UV method was used for the determination of the AI content in the TGAI/MUP by using external calibration. The active ingredient and impurities were further identified by MS, UV spectroscopy and ^{1}H-NMR. Water was determined by Karl Fischer titration. Method was validated for selectivity, linearity, recovery, repeatability and precision.

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required

Manufacturing process information may be entitled to confidential treatment

Montague, Kathryn V.

From: matthew.granahan@us.nufarm.com
Sent: Tuesday, March 25, 2014 2:31 PM
To: Montague, Kathryn V.
Subject: Re: 35935-38 amended label

Kay,

My mistake. I thought on all Tech source additions labeling was needed to be submitted.
There are no changes to the label resulting from these additional sources.

Matt

Sent from mobile device.

On Mar 25, 2014, at 1:10 PM, "Montague, Kathryn V." <Montague.Kathryn@epa.gov> wrote:

> Hi, Matt,
>
> R351 actions don't typically include a label amendment…can you point out what's changing on the label as a result of the new CSFs??
>
> Thanks,
> Kay
>
> **From:** matthew.granahan@us.nufarm.com [mailto:matthew.granahan@us.nufarm.com]
> **Sent:** Tuesday, March 25, 2014 2:03 PM
> **To:** Montague, Kathryn V.
> **Subject:** Re: 35935-38 amended label
>
> Kay,
>
> For the 2 Alternate Technical Source additions on 35935-38, via PRIA guided R351 actions, Nufarm wishes the attached label be used in review.
>
> Regards,
>
> Matt
>
> Matthew Granahan
> Regulatory Manager
> Nufarm Americas Inc.
> 11901 South Austin Avenue
> Alsip, IL 60803
> Phone: (708) 377-1330 (main)
> Phone: (708) 377-1421 (direct)
> Phone: [redacted] (cell)
> Fax: (708) 377-1425 (regulatory dept.)
> Email: matthew.granahan@us.nufarm.com

Personal privacy information

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From: "Montague, Kathryn V." <Montague.Kathryn@epa.gov>
To: 'matthew.granahan@us.nufarm.com' <matthew.granahan@us.nufarm.com>,
Date: 03/25/2014 12:32 PM
Subject: 35935-38 amended label

Hi, Matt,

I was able to squeeze this in...copies for your records.

The CSFs are still in review. One is due May 5, the other July 14.

Best Regards,
Kay

Kathryn V. Montague
Product Manager 23
OPPTS/OPP/RD/HB
1200 Pennsylvania Ave., NW
Mailcode 7505P
Washington, DC 20460
Phone: (703)305-1243

[attachment "35935-38 letter amended label 032514.pdf" deleted by Matthew Granahan/US/Nufarm]
[attachment "035935-00038.20140325.stampedaccepted.pdf" deleted by Matthew Granahan/US/Nufarm]

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Fax: +1 708 377 1333.

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Fax: +1 708 377 1333.

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

December 4, 2013

Via Overnight Courier

Geri McCann
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
CD Containing Revised Studies in Response to EPA Deficiency Letter Dated November 14, 2013
Revised MRIDs: 49226405, 49226406, 49226407 and 49226408

Dear Ms. McCann:

By way of this submission Nufarm wishes to address the deficiencies communicated via letter dated November 14, 2013 on the R351 PRIA Guided action for EPA Reg. No. 35935-58, submitted by Nufarm to the EPA on October 17, 2013, in which Nufarm desires to add an additional unregistered Technical Source (submitted as CSF Alt #3) as an alternate source on this registration.

To address these deficiencies please find on the attached CD the revised studies (MRIDs: 49226405, 49226406, 49226407 and 49226408) corrected as per the EPA communication. Additionally enclosed please find the EPA Deficiency Letter dated November 14, 2013, a revised Transmittal Document (with the revised areas in Red [all that has changed is the number of pages on these 4 studies from the previous Transmittal Document)] and an e-mail communication from December 4, 2013 between Nufarm and Teresa Downs.

Nufarm wishes to have these studies replace those previously submitted.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

RE: Root MRID Numbers Request - 2 Root MRID Numbers for Nufarm Limited (EPA Co. No. 35935)
Downs, Teresa
to:
matthew.granahan@us.nufarm.com, Montague, Kathryn V.
12/04/2013 07:25 AM
Hide Details
From: "Downs, Teresa" <Downs.Teresa@epa.gov>
To: "matthew.granahan@us.nufarm.com" <matthew.granahan@us.nufarm.com>,
"Montague, Kathryn V." <Montague.Kathryn@epa.gov>,
History: This message has been replied to.

Good morning, Matt,

Please CD containing just the replacement files for the 4 studies. You may include a brief letter to the attention of Geri McCann identifying the files as replacements to correct the deficiencies in these MRIDs, then attached a copy of our letter. Do not create a formal e-Submission. Let me know if you have any additional questions.

Teresa Downs
Information Services Branch
Information Technology and Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670

From: matthew.granahan@us.nufarm.com [mailto:matthew.granahan@us.nufarm.com]
Sent: Tuesday, December 03, 2013 12:54 PM
To: Downs, Teresa; Montague, Kathryn V.
Subject: RE: Root MRID Numbers Request - 2 Root MRID Numbers for Nufarm Limited (EPA Co. No. 35935)

Teresa / Kay,

Hope all is well with both of you!

Yesterday in the mail I received a deficiency notice (EPA Letter dated 11/24/2013 attached) on the following 4 studies- MRIDs: 49226405, 49226406, 49226407 and 49226408. Since receipt of this letter I have corrected these deficiencies and wish to resend these studies to the EPA for review of this new Dicamba Technical source under EPA Reg. No. 35935-38, on this R351 PRIA Guided Amendment.

Question:
Should I simply submit these studies via e-submission and include the EPA Deficiency letter, revised Transmittal Document and a Cover Letter? Or is there a better manner to resubmit these studies.

Regards,

Matt

Matthew Granahan
Regulatory Manager
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803

Phone: (708) 377-1330 (main)
Phone: (708) 377-1421 (direct)
Phone: [redacted] (cell)
Fax: (708) 377-1425 (regulatory dept.)
Email: matthew.granahan@us.nufarm.com

Personal privacy information

From: "Downs, Teresa" <Downs.Teresa@epa.gov>
To: "matthew.granahan@us.nufarm.com" <matthew.granahan@us.nufarm.com>, "Turner, Adrienne" <Turner.Adrienne@epa.gov>,
Date: 10/17/2013 09:11 AM
Subject: RE: Root MRID Numbers Request - 2 Root MRID Numbers for Nufarm Limited (EPA Co. No. 35935)

Good morning, Matt,

Your root MRIDs are 492264 and 492265.

Teresa Downs
Information Services Branch
Information Technology and Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670

From: matthew.granahan@us.nufarm.com [mailto:matthew.granahan@us.nufarm.com]
Sent: Wednesday, October 16, 2013 3:27 PM
To: Downs, Teresa; Turner, Adrienne
Subject: Root MRID Numbers Request - 2 Root MRID Numbers for Nufarm Limited (EPA Co. No. 35935)

Teresa / Adrienne,

I know the majority of the EPA is still being furloughed, but I sounds like federal work may commence soon. When you are back in the office, Nufarm Limited (EPA Co. No. 35935) would like to request 2 (two) new Root MRID Numbers.

Regards,

Matt

Matthew Granahan
Regulatory Manager
Nufarm Americas Inc.

11901 South Austin Avenue
Alsip, IL 60803
Phone: (708) 377-1330 (main)
Phone: (708) 377-1421 (direct)
Phone: [redacted] (cell)
Fax: (708) 377-1425 (regulatory dept.)
Email: matthew.granahan@us.nufarm.com

Personal privacy information

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Nufarm Americas Inc. and its affiliated companies.
Fax: +1 708 377 1333.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 14, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-OCT-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-03, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document. Please use these numbers in all future references to these documents. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. The rejected studies and their deficiencies are described below.

49226405

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

49226406

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submittedstudies) submitted to EPA. This statement must appearas page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

49226407

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49226408

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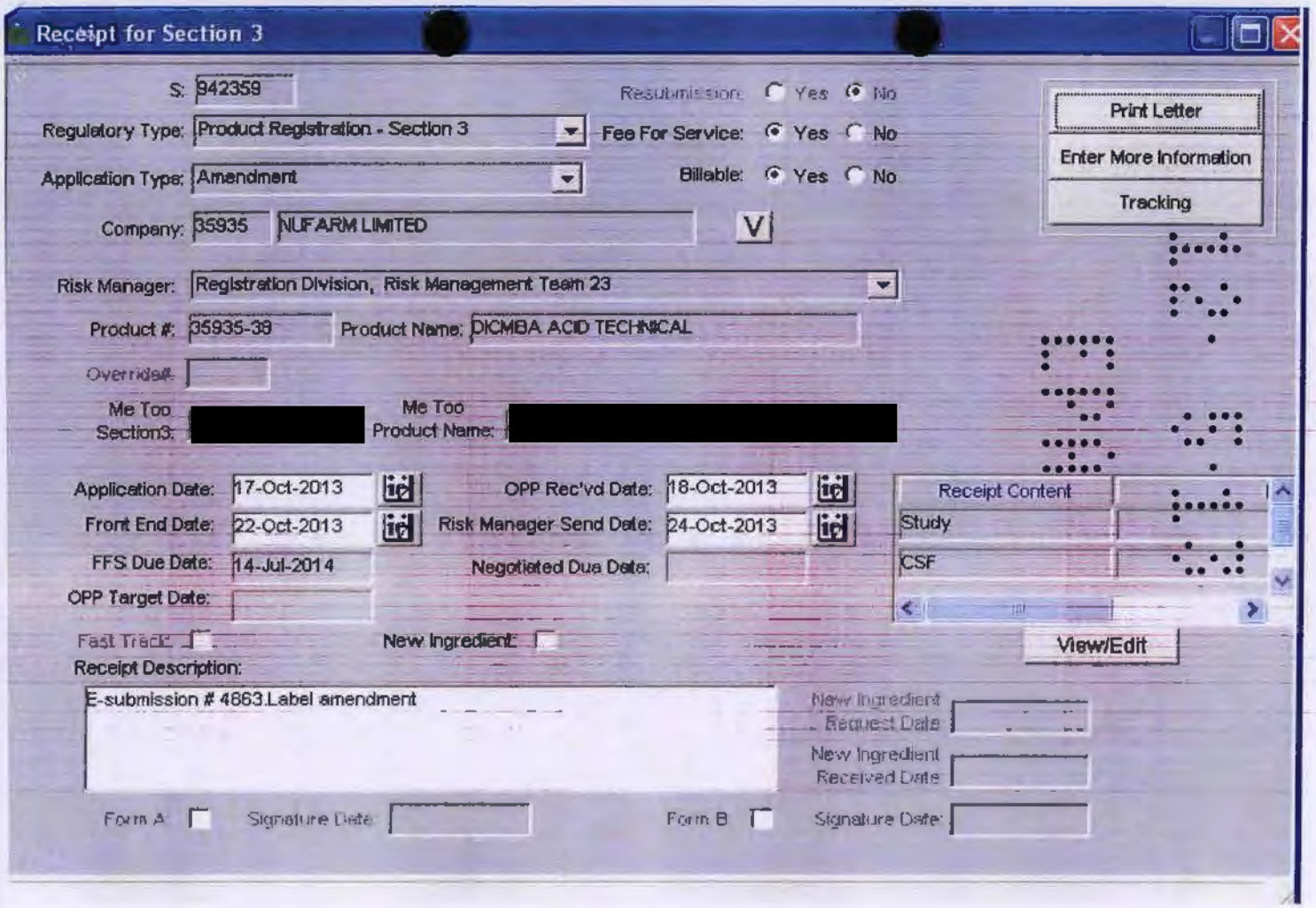

Product ingredient source information may be entitled to confidential treatment

49226400

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

October 17, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast Track PRIA Guided R351 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R351 action, adding a new unregistered source of active ingredient. It is our opinion that this action falls under category R351, amendment adding a new unregistered source of active ingredient and as such the PRIA fee of $11,996.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate an 8 month + 21 day review period by the Agency on this submission.

This new, submitted, unregistered source of active ingredient falls within the certified limits of the existing Basic CSF for this registration.

The CSF for this submission represents CSF Alternate #3. CSF Alternate #1 was submitted on August 14, 2013 and is pending at the Agency. CSF Alternate #2 was submitted August 16, 2013 and is pending at the Agency.

The submitted label is identical to the label submitted with the two pending submissions.

To process this request please find attached e-submission which includes the studies, revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

Nufarm Limited
4020 Aerial Center Parkway
Suite 101
Morrisville, NC 27560

Vol. No.	OPPTS No.	Study References	MRID No.
1	N/A	**Administrative Documents**	49226400
2	830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800.	Dicamba Acid Technical, NUP-13027 Product Identity and Process, OPPTS Sections 830.1550, 830.1600, 860.1620, 830.1670, 830.1700, 830.1750, 830.1800 Unpublished study by Nufarm Americas Inc. Study No. RTP-13-068-REG. 96 pages Total	49226401
3	830.1700	Qualitative and Quantitative Profile of the test substance Dicamba TC (Five Batch Analysis), OPPTS Section 830.1700. Unpublished study by Nufarm Americas Inc. Study No.1923.030.022.13. 224 pages Total	49226402
4	830.1700	Analysis for Tetra- to Octa- Chlorinated Dioxins and Furans in Five Batches of Dicamba TC, OPPTS Section 830.1700. Unpublished study by Nufarm Americas Inc. Study No. jscq_agro_0613. 208 pages Total	49226403
5	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6320, 830.7000, 830.7050, 830.7300, 830.7370.	Dicamba Physico-Chemical Properties. OPPTS Sections 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6320, 830.7000, 830.7050, 830.7300, 830.7370. Unpublished study by Nufarm Americas Inc. Study No. NAH0001. 82 pages Total	49226404
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Nufarm Limited
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REVISED STUDIES IN RED*

Vol. No.	OPPTS No.	Study References	MRID No.
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*Revised Per EPA Deficiency Letter November 14, 2013.

Memorandum

E-SUBMISSION

35935 -38

Date: 11/18/13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☐ fully accepted submission
- ☒ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 14, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-OCT-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-03, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document. Please use these numbers in all future references to these documents. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. The rejected studies and their deficiencies are described below.

49226405

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

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49226400
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

October 17, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast Track PRIA Guided R351 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R351 action, adding a new unregistered source of active ingredient. It is our opinion that this action falls under category R351, amendment adding a new unregistered source of active ingredient and as such the PRIA fee of $11,996.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate an 8 month + 21 day review period by the Agency on this submission.

This new, submitted, unregistered source of active ingredient falls within the certified limits of the existing Basic CSF for this registration.

The CSF for this submission represents CSF Alternate #3. CSF Alternate #1 was submitted on August 14, 2013 and is pending at the Agency. CSF Alternate #2 was submitted August 16, 2013 and is pending at the Agency.

The submitted label is identical to the label submitted with the two pending submissions.

To process this request please find attached e-submission which includes the studies, revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

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Sent 12/23/13

35935-38

Montague, Kathryn V.

From: matthew.granahan@us.nufarm.com
Sent: Monday, December 23, 2013 1:39 PM
To: Montague, Kathryn V.
Subject: MRID: 49258501 Deficiency Letter dated December 16, 2013
Attachments: 49258501.035935-00038.Technical Dicamba (NUP-13010).20131223.Dioxin Furan.pdf; 49258501.20131216.035935-00038.EPA Letter.Study Deficiency.pdf

Kay,

Hope all is well!
Nufarm is in receipt of the attached deficiency letter dated December 16, 2013 for an R351 PRIA Guided submission on 35935-38. The letter points out the STATEMENT OF DATA CONFIDENTIALITY CLAIM was lacking from MRID 49258501 (this is the Dioxin & Furan study submitted in effort of adding an additional source to 35938-38 - [redacted] I have revised the study MRID 49258501 to mitigate the concern raised in this letter - attached.

Is what is contained in the e-mail adequate for addressing this matter?
Would you rather this be submitted via e-submission?
Would you rather a different MRID be assigned to the study?

LDSD 5/5/14 THAT IS PRIA DATE!

already have another pending R351 on this — rec'd 8/13/13 (Diazinone) + 345 rec'd 8/16/13 (Diazinon) + Accepted 1/14/13.

Happy Holidays!

Regards,

Matt

Matthew Granahan
Regulatory Manager
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Phone: (708) 377-1330 (main)
Phone: (708) 377-1421 (direct)
Phone: [redacted] (cell)
Fax: (708) 377-1425 (regulatory dept.)
Email: matthew.granahan@us.nufarm.com

MRID 49258501 Emailed Teresa + Geri 1/15

*She uploaded new version 1/16/14

dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please delete, destroy, and do not save the message.

Nufarm Americas Inc. and its affiliated companies.
Fax: +1 708 377 1333.

E-SUBMISSION

35935 -38

Memorandum

Date: 12 / 16 / 13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ~~☒ fully accepted submission~~
- ☐ partially accepted submission
- ☒ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 16, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 22-NOV-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49258501

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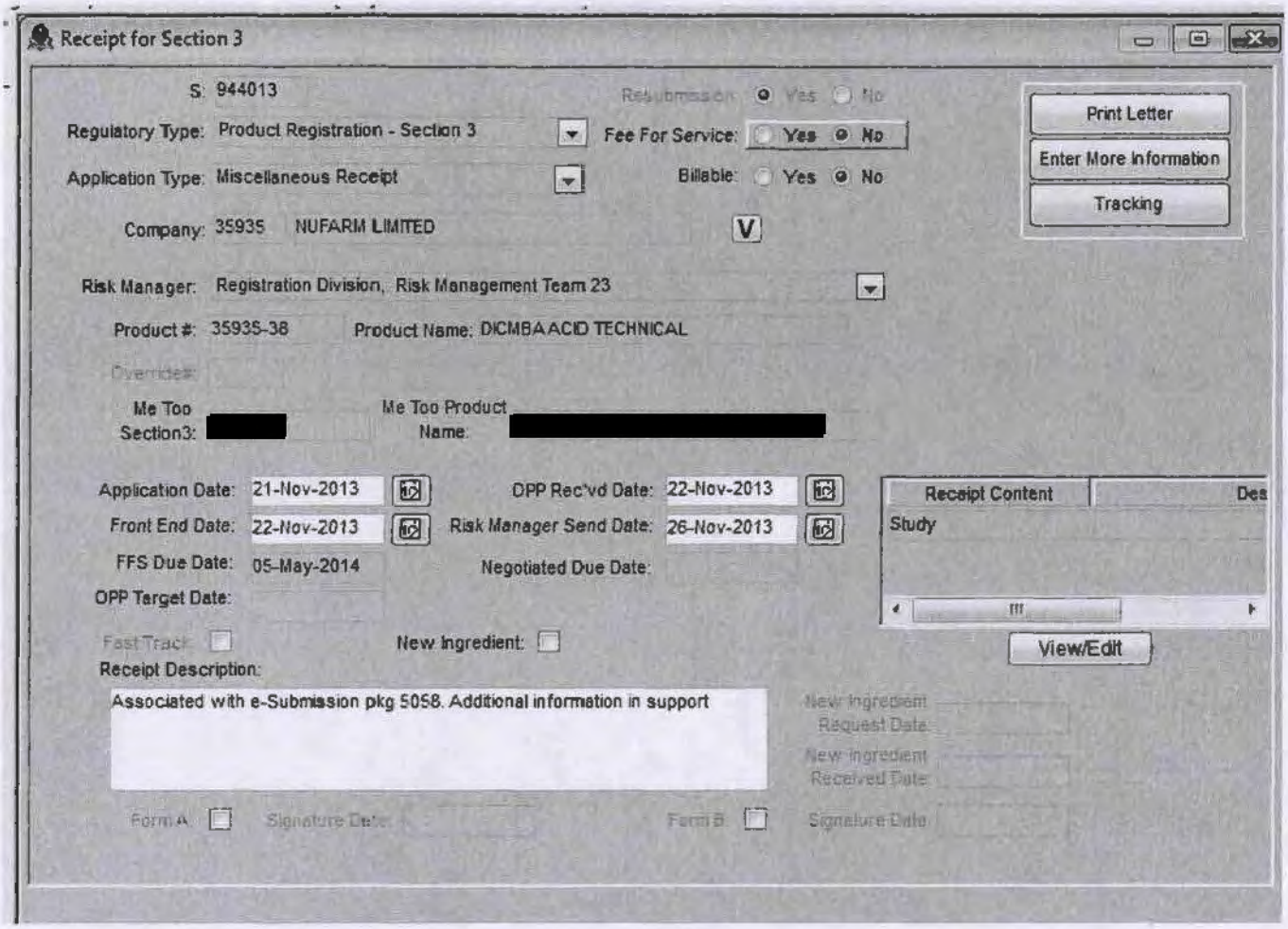

Product ingredient source information may be entitled to confidential treatment

49258500

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November 21, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission
Additional Study – Dioxin & Furan Analysis on Submitted Source

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting an additional study to the pending PRIA Guided R351 action, originally submitted August 13, 2013, by which Nufarm is intending to add a new unregistered source of active ingredient.

To process this request please find the attached e-submission which includes the study, transmittal document, EPA Receipt of Amendment and a copy of this cover letter.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

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Vol. No.	OPPTS No.	Study References	MRID No.
1	N/A	**Administrative Documents**	49258500
2	830.1700, 830.1800.	Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI. OPPTS Section 830.1700, 830.1800. Unpublished study by Nufarm Americas Inc. Study No. 01.19495.01.001. 128 pages Total	49258501

49258500

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November 21, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission
Additional Study – Dioxin & Furan Analysis on Submitted Source

Dear Ms. Montague:

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To process this request please find the attached e-submission which includes the study, transmittal document, EPA Receipt of Amendment and a copy of this cover letter.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

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4020 Aerial Center Parkway
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Vol. No.	OPPTS No.	Study References	MRID No.
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21-Day Screen Completed by Contractor

21-Day Expires on 11-8-13

Jacket # 35935-38
MRID# _____

Content Screen: Recommend to [Pass]/Fail

11-3 Review: Pass/Fail/ [NA]

Overall Status: Recommend to [Pass]/Fail

Transfer This Jacket to:

STEPHEN Jeffries

23

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10/18/13

Experts In-Processing Signature: MP Date 10/25 Fee Paid: Yes ✓

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 35935-38	EPA Receipt Date: 10/18/13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) * No inerts to review	yes	no			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes X	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**					X
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* No studies submitted w/ application
* Technical & impurities only — no merits to review
* amendment PASSED

MC

MRID: NONE

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Ageney to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 24, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
OR PAY ON-LINE at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-484122
EPA File Symbol or Registration Number: 35935-38
Product Name: DICMBA ACID TECHNICAL
EPA Receipt Date: 18-Oct-2013
EPA Company Number: 35935
Company Name: NUFARM LIMITED

MATTHEW GRANAHAN
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560-

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

The PRIA 3 fees increased by 5% effective October 1, 2013. Please go to http://www.epa.gov/pesticides/fees/tool/category-table.html to see the new PRIA 3 fees. For your application, and additional fee of $600 is due. Please remit payment within 14 days to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197

Payment Still Due

Please complete the 21-day review and forward to the appropriate regulatory division.

Regulatory divisions, please check with Mick Yanchulis (347-0237) to ensure full payment has been made before beginning any substantive work on this action.

M

Fee for Service

{942359F~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 23

Receipt No. S- 942359

EPA File Symbol/Reg. No. 35935-38

Pin-Punch Date: 10/18/2013

□ This item is NOT subject to FFS action.

Action Code:

Requested: R351

Granted: R351

Amount Due: $ 12,596

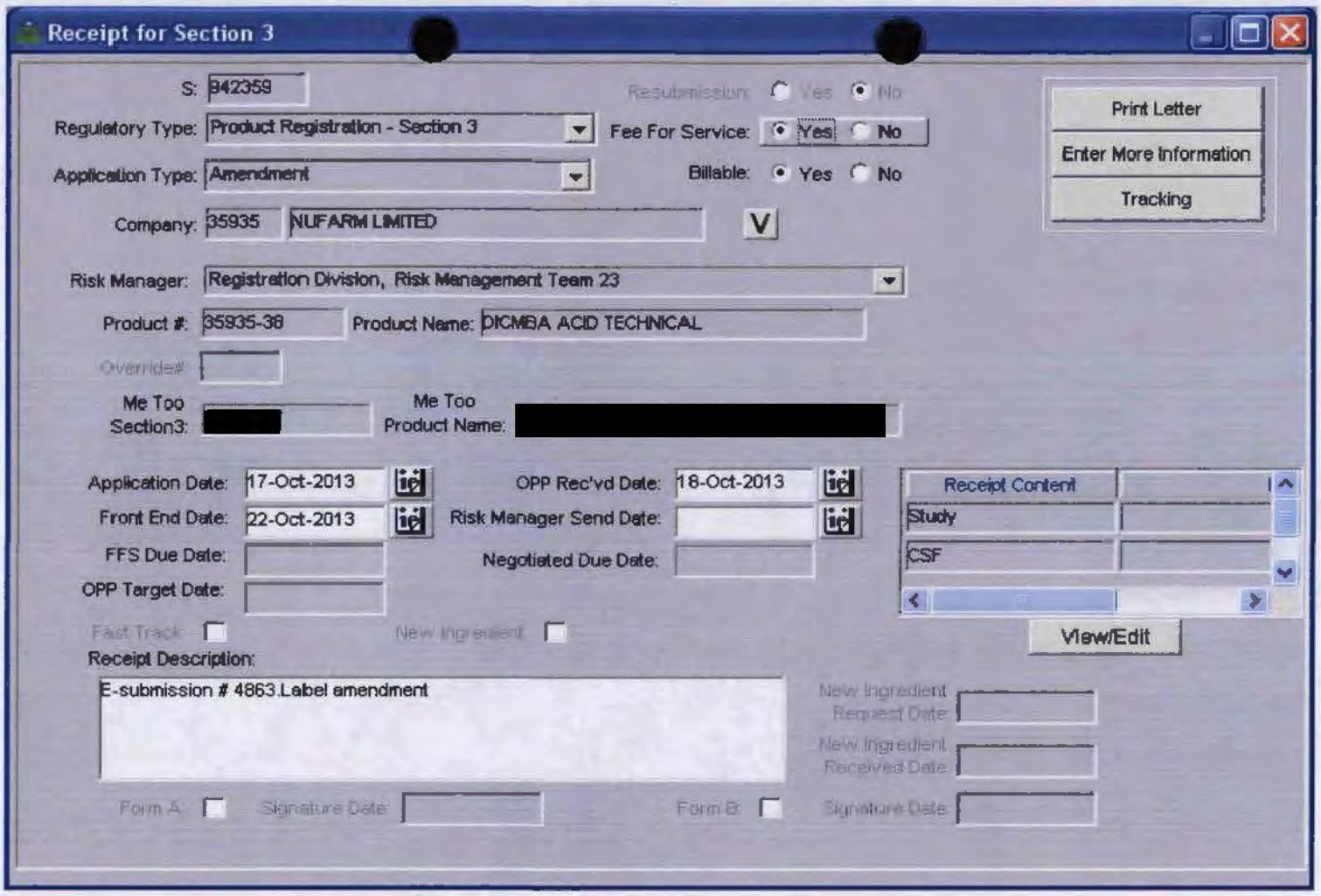
Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Steve Schaible Date: 10/24/13

Remarks: registrant paid FY13 fee - added $ due

E-SUBMISSION



Product ingredient source information may be entitled to confidential treatment

E-SUBMISSION

Pay.gov Payment Confirmation : PRIA Service Fees

paygovadmin to: matthew.granahan@us.nufarm.com 10/17/2013 08:36 AM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25CPN49P
Agency Tracking ID: 745178115l6
Transaction Type: Sale
Transaction Date: Oct 17, 2013 9:36:15 AM

Account Holder Name: Matthew Granahan
Transaction Amount: $11,996.00
Billing Address: 11901 South Austin Ave.
City: Alsip
State/Province: IL
Zip/Postal Code: 60803
Country: USA
Card Type: MasterCard
Card Number: **********6875

Decision Number:
Registration Number: 35935-38
Company Name: Nufarm Limited
Company Number: 35935
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

October 17, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast Track PRIA Guided R351 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R351 action, adding a new unregistered source of active ingredient. It is our opinion that this action falls under category R351, amendment adding a new unregistered source of active ingredient and as such the PRIA fee of $11,996.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate an 8 month + 21 day review period by the Agency on this submission.

This new, submitted, unregistered source of active ingredient falls within the certified limits of the existing Basic CSF for this registration.

The CSF for this submission represents CSF Alternate #3. CSF Alternate #1 was submitted on August 14, 2013 and is pending at the Agency. CSF Alternate #2 was submitted August 16, 2013 and is pending at the Agency.

The submitted label is identical to the label submitted with the two pending submissions.

To process this request please find attached e-submission which includes the studies, revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

E-SUBMISSION

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathryn Montague	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: 100-905, 33658-12, 35935-38, [redacted] 51036-296,
EPA Reg. No. 7969-132, 80967-8, 83520-8, 9468-45

Product Name Dicamba Technical Registrations

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

R351 - Amendment adding a new unregistered source of AI
$11,996
8 month review

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	50 - 250 lbs, bulk	[X]

6. Manner in Which Label is Affixed to Product: [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other Self-Adhesive Integrated Label/Booklet

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Granahan	Regulatory Manager	(708) 377-1421

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
[signature]	Regulatory Manager	Matthew Granahan matthew.granahan@us.nufarm.com	10/17/2013

E-SUBMISSION

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-[redacted]7, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	35935-38
	Product Name Dicamba Acid Technical
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 02/23/07, 08/13/2013 (pending), 08/16/13 (pending), 10/17/13 (pending)

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Dicamba (3,6-dichloro-o-anisic acid)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Dicamba (3,6-dichloro-o-anisic acid)	[redacted]	[redacted]

Product ingredient source information may be entitled to confidential treatment

Signature	Name and Title	Date
	Matthew Granahan Regulatory Manager	10/17/2013

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 (708) 377-1421	35935-38
Active Ingredient(s) and/or representative test compound(s) Dicamba (3,6-dichloro-o-anisic acid)	Date 10/17/2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Crop, Terrestrial Feed Crop, Terrestrial Nonfood Crop, Forestry, Aquatic Noncrop, Domestic Outdoor	Product Name Dicamba Acid Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

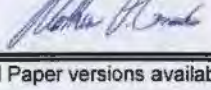
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	10/17/2013	Matthew Granahan Regulatory Manager

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 1 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS Series 830	**Product Properties**				
830.1550	Product identity and composition	49226401	Nufarm Americas Inc.	Own	
830.1600	Description of materials used to produce the product	49226401	Nufarm Americas Inc.	Own	
830.1620	Description of production process	49226401	Nufarm Americas Inc.	Own	
830.1650	Description of formulation process				1
830.1670	Discussion of formation of impurities	49226401	Nufarm Americas Inc.	Own	
830.1700	Preliminary analysis	49226401, 49226402, 49226403	Nufarm Americas Inc.	Own	
830.1750	Certified limits	49226401	Nufarm Americas Inc.	Own	
830.1800	Enforcement analytical method	49226401	Nufarm Americas Inc.	Own	
830.1900	Submittal of sample				2
830.6302	Color	49226404	Nufarm Americas Inc.	Own	
830.6303	Physical state	49226404	Nufarm Americas Inc.	Own	
830.6304	Odor	49226404	Nufarm Americas Inc.	Own	
Signature		Name and Title Matthew Granahan, Regulatory Manager		Date Oct. 17, 2013	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 2 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	49226404	Nufarm Americas Inc.	Own	
830.6314	Oxidation/reduction: chemical incompatibility	49226404	Nufarm Americas Inc.	Own	
830.6315	Flammability	49226404	Nufarm Americas Inc.	Own	
830.6316	Explodability	49226404	Nufarm Americas Inc.	Own	
830.6317	Storage stability	49226404	Nufarm Americas Inc.	Own	
830.6319	Miscibility				3
830.6320	Corrosion characteristics	49226404	Nufarm Americas Inc.	Own	
830.6321	Dielectric breakdown voltage				4
830.7000	pH	49226404	Nufarm Americas Inc.	Own	
830.7050	UV/Visible absorption	49226404	Nufarm Americas Inc.	Own	
830.7100	Viscosity				5
830.7200	Melting point/melting range	49226405	Nufarm Americas Inc.	Own	
830.7220	Boiling point/boiling range				6
830.7300	Density/relative density/bulk density	49226404	Nufarm Americas Inc.	Own	

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 3 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation constants in water	49226404	Nufarm Americas Inc.	Own	
830.7520	Particle size, fiber length, and diameter distribution				7
830.7550	Partition coefficient (n-octanol/water), shake flask method	49226406	Nufarm Americas Inc.	Own	
830.7560	Partition coefficient (n-octanol/water), generator column method				8
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography				9
830.7840	Water solubility: column elution method; shake flask method	49226407	Nufarm Americas Inc.	Own	
830.7860	Water solubility: generator column method				10
830.7950	Vapor pressure	49226408	Nufarm Americas Inc.	Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 4 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340	**Toxicology**				
870.1100	Acute oral toxicity - rat	Cite-all	-	PAY	
870.1200	Acute dermal toxicity - rat	Cite-all	-	PAY	
870.1300	Acute inhalation toxicity - rat	Cite-all	-	PAY	
870.2400	Primary eye irritation - rabbit	Cite-all	-	PAY	
870.2500	Primary dermal irritation -rabbit	Cite-all	-	PAY	
870.2600	Dermal sensitization - Guinea pig	Cite-all	-	PAY	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 5 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements					
Nufarm Limited made offers-to-pay to the following companies on the data submitters list of April 8, 2013					
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Syngenta Crop Protection, LLC (100)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Americas Inc. (228)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		The Scotts Company (239)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		BASF Corporation (241)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		E. I. DuPont De Nemours and Company (352)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Bayer Environmental Science (432)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Monsanto Company (524)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Scotts Company, The (538)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Lebanon Seaboard Corporation (961)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		PBI/Gordon Corp (2217)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		BASF Corporation (7969)	PAY	

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Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		The Andersons Lawn Fertilizer Division (9198)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Ritter Chemical, LLC (9468)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Chemsico (9688)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Loveland Products, Inc. (34704)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Limited (35935)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Albaugh Inc (42750)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Dow AgroSciences LLC (62719)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Spray Drift Task Force (66607)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Repar Corp (69361)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Petro-Canada Lubricants Inc., A Suncor (69526)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Gharda USA, Inc. (70907)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Inc. (71368)	OWN	

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DATA MATRIX

Date: October 17, 2013	EPA Reg. No./File Symbol 35935-38	Page 7 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Outdoor Residential Exposure Task Force (71754)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agricultural Reentry Task Force (71755)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Bayer Advanced (72155)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Swiss Farms Products (73327)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		FIFRA Endangered Species Task Force (73989)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Residential Exposure Joint Venture (74888)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agricultural Handler Exposure Task Force (75234)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Mey Corporation (80967)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Libertas Now, Inc. (81442)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Direct Ag Source, LLC (8322)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Tacoma Ag, LLC (83520)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Gharda Generics, Inc (84836)	PAY	

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agrium Advanced Technologies (U.S.) Inc (84886)	PAY	

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

EXPLANATORY NOTES

Note #	Guideline Ref. #	Name of Test	Comment
1	830.1650	Description of formulation process	Not applicable to TGAI product. Guideline 830.1620 is primary.
2	830.1900	Submittal of samples	Not applicable unless specifically requested by the Agency.
3	830.6319	Miscibility	Not applicable to TGAI.
4	830.6321	Dielectric breakdown voltage	Not applicable to TGAI.
5	830.7100	Viscosity	Not applicable to TGAI.
6	830.7220	Boiling point/boiling range	Not applicable because product is not a liquid.
7	830.7520	Particle size, fiber length, and diameter distribution	Not applicable because product is not fibrous.
8	830.7560	Partition coefficient (n-octanol/water), generator column method	Addressed under 830.7840
9	830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	Addressed under 830.7840
10	830.7860	Water solubility: generator column method	Addressed under 830.7840

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
				Own	
				Own	
				Own	
					1
				Own	
				Own	
				Own	
				Own	
					2
				Own	
				Own	
				Own	

Signature	Name and Title	Date
[signature]	Matthew Granahan, Regulatory Manager	Oct. 17, 2013

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Own	
				Own	
				Own	
				Own	
				Own	
					3
				Own	
					4
				Own	
[redacted]				Own	
					5
				Own	
					6
				Own	
				Own	

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Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					7
				Own	
					8
					9
				Own	
					10
				Own	

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Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	

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Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				PAY	
				OWN	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				OWN	
				PAY	
				PAY	
				OWN	
				PAY	
				PAY	
				PAY	

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Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				OWN	
				OWN	
				OWN	
				PAY	
				OWN	
				OWN	
				OWN	
				OWN	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	**Date Submitted to EPA**	**Electronic file name**
35935-38	10/17/2013	035935-00038.20131017.Amendment

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

10/17/2013

Date

Matthew Granahan

Name (typed)

Regulatory Manager

Title

E-SUBMISSION

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid).	98.0%
OTHER INGREDIENTS:.	2.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 35935-38
EPA EST. NO.

MANUFACTURED FOR
NUFARM LIMITED
4020 AERIAL CENTER PARKWAY
SUITE 101
MORRISVILLE, NC 27560

Nufarm

NET WEIGHT LBS. (KG)

035935-00038.20131017.Amendment

E-SUBMISSION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF SWALLOWED. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact (877) 325-1840 for emergency medical treatment information.	
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.	

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds. Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For The Following Uses:
(1) Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf, and sod farms;
(2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
(3) Uses for experimental purposes that are in compliance with U.S.EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment or mixing equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV101713)

LABEL HISTORY

FILE NAME	RV DATE	Comments
035935-00038.20100218.MASTER	RV021810	EPA SAL
035935-00038.20130813.Amendment	RV081313	Amendment
035935-00038.20130816.Amendment	RV081613	Amendment
035935-00038.20131017.Amendment	RV101713	Amendment

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid)	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 35935-38
EPA EST. NO.

MANUFACTURED FOR
NUFARM LIMITED
4020 AERIAL CENTER PARKWAY
SUITE 101
MORRISVILLE, NC 27560

Nufarm

NET WEIGHT LBS. (KG)

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E-SUBMISSION

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HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF SWALLOWED. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact (877) 325-1840 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds. Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For The Following Uses:
(1) Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf, and sod farms;
(2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
(3) Uses for experimental purposes that are in compliance with U.S.EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment or mixing equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV101713)

LABEL HISTORY

FILE NAME	RV DATE	Comments
035935-00038.20100218.MASTER	RV021810	EPA SAL
035935-00038.20130813.Amendment	RV081313	Amendment
035935-00038.20130816.Amendment	RV081613	Amendment
035935-00038.20131017.Amendment	RV101713	Amendment

Material Sent for Data Extraction

Reg # 35935-38

Description: _____

Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☐ Notification Dated _____
- ☒ New CSF(s) Dated 4-17-14 amt #1
- ☐ Other: _____

Decision #: _____

Other Action/Comments: _____

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Kathryn Montague

Phone: (703)305-0123 Division: RD/PM Team 23

Date: 7-7-14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Matthew Granahan
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

APR 29 2014

Dear Mr. Granahan:

SUBJECT: Alternate (#1) Confidential Statement of Formula (CSF) – Adding a New Unregistered Source of Active Ingredient
Dicamba Acid Technical
EPA Registration No. 35935-38
Your Submission Dated August 13, 2013
Decision # 482084

The Agency has completed its review of the alternate CSF (#1), dated April 17, 2014, and has determined it is acceptable. This alternate CSF supersedes the alternate CSF dated August 13, 2013. A copy has been placed in the file as part of the record. A copy of the review is enclosed.

Sincerely yours,

Kathryn V. Montague
Product Manager (23)
Herbicide Branch
Registration Division (7505P)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP Barcode No.: D416604 File Symbol No.: 35935-38 Decision No.: 482084
PC Code: 029801 Action Code: R 351
Food Use: NO Product Name: Dicamba Acid Technical

Date: April 22, 2014

SUBJECT: Product Chemistry Review of the Manufacturing Use Product, Dicamba Acid Technical

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch/RD (7505P)
Registration Division (7505P)

Bruce F. Kitchens
22 Apr 2014
SBm 4/22/14

TO: RM #23, Kathryn V. Montague/Dianne Morgan
Herbicide Branch
Registration Division (7505P)

INTRODUCTION:

The registrant, Nufarm Limited, is submitting product chemistry data to support a requested amendment for the registered manufacturing use product, Dicamba Acid Technical. The proposed amendment and the product chemistry data are the result of additional production sites for the technical product. The active ingredient in this product is Dicamba acid at a label nominal concentration of 98.0% a.i. This product is intended for use in the manufacture of herbicide end-use products. With this submission, the registrant has submitted product chemistry data contained in MRID# 492585-01. During the course of this review, the registrant submitted a revised alternate CSF dated 17 Apr 2013 to correct an error in the name and address of the alternate producer. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.

2. This study intended to qualitatively and quantitatively determine targeted impurities of toxicological concern in the active ingredient at levels $\geq 0.1\%$. See the confidential appendix for details and results of the analysis. This analysis was conducted on Dicamba acid produced at the following alternate production site:

[redacted]

Product ingredient source information may be entitled to confidential treatment

DP Barcode No.: 416604 File Symbol No.: 35935-38 Decision No.: 482084
PC Code: 029801 Action Code: R 351
Food Use: No Product Name: Dicamba Acid Technical

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The revised alternate formula CSF for the manufacturing use product, Dicamba Acid Technical dated 17 Apr 2014 is acceptable. This alternate CSF supersedes the alternate CSF dated 13 Aug 2013.

2. This submission satisfies the data requirements as specified in 40 CFR 158.170 and 158.180 with respect to preliminary analysis and the enforcement analytical method.

3. The revised alternate CSF for the manufacturing use product, Dicamba Acid Technical dated 17 Apr 2014 meets the criteria specified in 40 CFR 158. 43 with respect to alternate formulations.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

DATE OUT: 04/08/14

04/09/14

FROM: Indira Gairola
Product Chemistry Team
Technical Review Branch/RD (7505P)

4/9/14

TO: Diana Morgan /Kathryn Montague PM 23
Herbicide Branch /RD (7505P)

DP BARCODE No.: 415156
File Symbol No.: 35935-38
COMPANY: NUFARM LIMITED.
PCC: 029801
Decision No. 482084
Chemical Name: Dicamba
CAS No. 1918-00-9
USE: Herbicide Branch (Solid)

INTRODUCTION:

GENICS INC. is submitting amendment to include alternate#1 CSF dated 08/13/13 for the unregistered source of active ingredient for the subject product Dicamba Acid Technical for Dicamba Acid that will be produced by [redacted] Applicant submitted Product Chemistry Guideline reference 830 Subgroup A data with MRID #s 491904-01, -03, 472671-01, 470745-03, to -04, &491904-03 to -02 to support alternate formulation CSF dated 08/13/13.
TRB has been asked to determine the acceptability of the product chemistry data and the proposed alternate formulation CSF dated 08/13/13.

SUMMARY OF FINDINGS:

1. Group A guidelines: 830.1550 (product identity & composition)

The active ingredient was adequately described (MRID # 491904-01. The nominal concentration of the active ingredient (100.0% in the confidential attachment in MRID 491904-01 and CSF dated 08/13/13) matches the average derived from the 5-batch preliminary analysis in MRID#491904-01, -02). The content of the A.I. matches that on the

830.1600 (description of materials used to produce the product)
The submitted data are acceptable. MSDSs of all the starting materials, and their suppliers and purities are provided in the study (MRID #491904-01). The information presented meets the data requirements for 40 CFR 158.325.

830.1620 (description of production process)
The submitted data are acceptable. Description of the production process, chemical pathways, flow charts and quality control measures were provided in MRID #491904-01. The information presented meets the data requirements for 40 CFR 158.330.

830.1670 (discussion on the formation of impurities)
The submitted data are acceptable. Potential impurities were identified and quantified as part of the five-batch analysis (MRID #491904-01). Impurities negligible in Dicamba acid (MRID #4912491-01. Insoluble impurities may include various salts from the overall process. No nitrosamines are expected to be formed in the manufacturing process of Dicamba acid since there are no secondary amines present in the synthesis. Polychlorinated biphenyls, dibenzodioxins and dibenzofurans are not expected to be present in the final product (MRID #491904-02)
The information presented meets the data requirements for 40 CFR 158.340

830.1700 (preliminary analysis)
The submitted data are acceptable. Results are presented for a five-batch analysis (MRID 4912491-02). Applicant has submitted (MRID #491904-02).The nominal concentrations of the A.I. were 99.22 to 99.62% (average 99.52% in MRID # 491249-02). The information presented meets the data requirements for 40 CFR 158.345.

830.1800 (Enforcement analytical method). Analysis of Dicamba is done by high performance liquid chromatography, (HPLC) using ultra-violet detection. The Dicamba TGAI is dissolved in Acetonitrile. The separation is done on a HPLC column and the active is calculated based on external standard methodology.

CONCLUSIONS:

The TRB has reviewed the proposed alternate CSF dated 08/13/13 and product chemistry data submitted for the subject product Dicamba Acid Technical and has concluded that:

1. The product chemistry data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of the production process), 830.1670 (discussion of the formation of impurities), 830.1700 (preliminary analysis), 830.1750 (certified limits) and 830.1800 (enforcement analytical method) are acceptable.

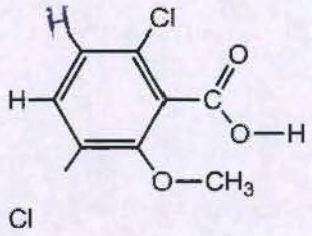
2. The proposed alternate CSF dated 08/13/13 is acceptable. The upper and lower certified limits for the A.I. are within EPA's Standard Certified Limits.

OPPTS 830.1550- Product Identity

Active Ingredient Identity:

CAS No.:	1918-00-9
Common name/alias:	Dicamba
Chemical Names:	
IUPAC:	3,6-dichloro-*o*-anisic acid or 3,6-dichloro-2-methoxybenzoic acid
CAS:	3,6-dichloro-2-methoxybenzoic acid
Molecular formula:	$C_8H_6Cl_2O_3$
Molecular weight:	221.04
Structure:	

Test Article: NUP-13010 – Nufarm Technical Dicamba



SUB GROUP A PRODUCT NAME: Dicamba Technical

. GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product Identity & Disclosure of Ingredients	491904-01	A	CSF 08/13/13
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	491904-01	A	
830.1670	Discussion of Impurities	491904-01	A	
830.1700	Preliminary Analysis	491904-02	A	
830.1750	Certification of Limits	491904-02	A	CSF 08/13/13
830.1800	Analytical Methods	491904-01	A	

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.
[2] Refer to CBI Appendix A for details.

Morgan, Dianne

From: matthew.granahan@us.nufarm.com
Sent: Friday, April 18, 2014 11:49 AM
To: Morgan, Dianne
Cc: Montague, Kathryn V.
Subject: Re: *Confidential: Fw: 35935-38 CSF Alt 1 Submission - Confidential

Per Kay label review not required- there should be a e-mail in the jacket to that effect.

Sent from mobile device.

On Apr 18, 2014, at 10:45 AM, "Morgan, Dianne" <Morgan.Dianne@epa.gov> wrote:

> Hi Matthew,
>
> Please send me a copy of the labeling for this product via PDF. Thanks!
>
> **From:** matthew.granahan@us.nufarm.com [mailto:matthew.granahan@us.nufarm.com]
> **Sent:** Thursday, April 17, 2014 3:16 PM
> **To:** Kitchens, Bruce
> **Cc:** Morgan, Dianne
> **Subject:** *Confidential: Fw: 35935-38 CSF Alt 1 Submission - Confidential
>
> Bruce,
>
> I just spoke with Dianne and resulting from that conversation I am sending this e-mail in effort of answering the question on the CSF Alt 1 submission for 35935-38 - sounds like her CPU is being updated and she is currently unable to access e-mails.
>
> Questions please let me know.
>
> Regards,
>
> Matt
>
> Matthew Granahan
> Regulatory Manager
> Nufarm Americas Inc.
> 11901 South Austin Avenue
> Alsip, IL 60803
> Phone: (708) 377-1330 (main)
> Phone: (708) 377-1421 (direct)
> Phone: [redacted] (cell)
> Fax: (708) 377-1425 (regulatory dept.)
> Email: matthew.granahan@us.nufarm.com
>
> *Personal privacy information*
>
>

---- Forwarded by Matthew Granahan/US/Nufarm on 04/17/2014 02:09 PM ----

From: Matthew Granahan/US/Nufarm
To: Morgan.dianne@Epa.gov,
Cc: Nathan Ehresman/US/Nufarm@Nufarm, Anson Cooke/US/Nufarm@NUFARM
Date: 04/17/2014 09:33 AM
Subject: 35935-38 CSF Alt 1 Submission - Confidential

Dianne,

Hope all is well!
Sorry for the delay in reply; Nufarm needed to touch base across seas to make sure the reply is accurate.

The discrepancy you called to my attention is resulting from a relatively recent name change for this facility. The former name of the facility producing Dicamba Technical (NUP-13010) was [redacted]

I have revised the CSF Alternate 1 to reflect this change in facility name; it should be noted [redacted]

Please let me know if any additional information is needed to register this Dicamba TGAI source on 35935-38. As mentioned in conversation, Dicamba is very short supply this 2014 growing season and any expedition for this source would be greatly appreciated by the growers across the U.S.

Hope you have an excellent weekend!

<M1.2.gif>

Regards,

Matt

Matthew Granahan
Regulatory Manager
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Phone: (708) 377-1330 (main)
Phone: (708) 377-1421 (direct)
Phone: [redacted] (cell)
Fax: (708) 377-1425 (regulatory dept.)
Email: matthew.granahan@us.nufarm.com

Personal privacy information

Product ingredient source information may be entitled to confidential treatment

Montague, Kathryn V.

From: matthew.granahan@us.nufarm.com
Sent: Tuesday, March 25, 2014 2:31 PM
To: Montague, Kathryn V.
Subject: Re: 35935-38 amended label

Kay,

My mistake. I thought on all Tech source additions labeling was needed to be submitted.
There are no changes to the label resulting from these additional sources.

Matt

Sent from mobile device.

On Mar 25, 2014, at 1:10 PM, "Montague, Kathryn V." <Montague.Kathryn@epa.gov> wrote:

> Hi, Matt,
>
> R351 actions don't typically include a label amendment…can you point out what's changing on the label as a result of the new CSFs??
>
> Thanks,
> Kay
>
> **From:** matthew.granahan@us.nufarm.com [mailto:matthew.granahan@us.nufarm.com]
> **Sent:** Tuesday, March 25, 2014 2:03 PM
> **To:** Montague, Kathryn V.
> **Subject:** Re: 35935-38 amended label
>
> Kay,
>
> For the 2 Alternate Technical Source additions on 35935-38, via PRIA guided R351 actions, Nufarm wishes the attached label be used in review.
>
> Regards,
>
> Matt
>
> Matthew Granahan
> Regulatory Manager
> Nufarm Americas Inc.
> 11901 South Austin Avenue
> Alsip, IL 60803
> Phone: (708) 377-1330 (main)
> Phone: (708) 377-1421 (direct)
> Phone: [redacted] (cell)
> Fax: (708) 377-1425 (regulatory dept.)
> Email: matthew.granahan@us.nufarm.com

Personal privacy information

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From: "Montague, Kathryn V." <Montague.Kathryn@epa.gov>
To: "matthew.granahan@us.nufarm.com" <matthew.granahan@us.nufarm.com>,
Date: 03/25/2014 12:32 PM
Subject: 35935-38 amended label

Hi, Matt,

I was able to squeeze this in...copies for your records.

The CSFs are still in review. One is due May 5, the other July 14.

Best Regards,
Kay

Kathryn V. Montague
Product Manager 23
OPPTS/OPP/RD/HB
1200 Pennsylvania Ave., NW
Mailcode 7505P
Washington, DC 20460
Phone: (703)305-1243

[attachment "35935-38 letter amended label 032514.pdf" deleted by Matthew Granahan/US/Nufarm]
[attachment "035935-00038.20140325.stampedaccepted.pdf" deleted by Matthew Granahan/US/Nufarm]

****

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Nufarm Americas Inc. and its affiliated companies.
Fax: +1 708 377 1333.

****

Nufarm Americas Inc. and its affiliated companies.
Fax: +1 708 377 1333.

Morgan, Dianne

From: Montague, Kathryn V.
Sent: Friday, December 06, 2013 11:35 AM
To: Downs, Teresa
Cc: Morgan, Dianne
Subject: MRID #49258501

Hi, Teresa,

Just want to make sure this study (resubmission for a pending PRIA action) is on your list/radar screen, as it's listed in Documentum as not yet having 11-3 review. It came in on 11/22, so I'm thinking it may still in your pending actions.

Thanks,
Kay

Kathryn V. Montague
Product Manager 23
OPPTS/OPP/RD/HB
1200 Pennsylvania Ave., NW
Mailcode 7505P
Washington, DC 20460
Phone: (703)305-1243

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 26, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NATHAN P. EHRESMAN
NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560-

PRODUCT NAME: DICMBA ACID TECHNICAL
COMPANY NAME: NUFARM LIMITED
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 35935-38
EPA RECEIPT DATE: 11/22/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{944013o~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 23

Receipt No. S- 944013

EPA File Symbol/Reg. No. 35935-38

Pin-Punch Date: 11/22/2013

☑ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: _____ Date: 11-26-13

Remarks:

-resubmission

E-SUBMISSION

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

November 21, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission
Additional Study – Dioxin & Furan Analysis on Submitted Source

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting an additional study to the pending PRIA Guided R351 action, originally submitted August 13, 2013, by which Nufarm is intending to add a new unregistered source of active ingredient.

To process this request please find the attached e-submission which includes the study, transmittal document, EPA Receipt of Amendment and a copy of this cover letter.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

E-SUBMISSION

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

November 21, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission
Additional Study – Dioxin & Furan Analysis on Submitted Source

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting an additional study to the pending PRIA Guided R351 action, originally submitted August 13, 2013, by which Nufarm is intending to add a new unregistered source of active ingredient.

To process this request please find the attached e-submission which includes the study, transmittal document, EPA Receipt of Amendment and a copy of this cover letter.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

E-SUBMISSION

Nufarm Limited
4020 Aerial Center Parkway
Suite 101
Morrisville, NC 27560

Vol. No.	OPPTS No.	Study References	MRID No.
1	N/A	**Administrative Documents**	49258500
2	830.1700, 830.1800.	Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI. OPPTS Section 830.1700, 830.1800. Unpublished study by Nufarm Americas Inc. Study No. 01.19495.01.001. 128 pages Total	49258501

Dicamba Acid Technical, EPA Reg. No. 35935-38 - Dioxin Furan Study

Matthew Granahan to: Montague.kathryn 11/21/2013 02:12 PM
Cc: Nathan Ehresman
Bcc: Anson Cooke

Kay,

Hope all is well!

Wanted to give you a head's up that Nufarm will be submitting an additional study (via e-submission) on the Dicamba Acid Technical, EPA Reg. No. 35935-38, PRIA Guided Amendment, submitted August 13, 2013. This study (attached) {MRID 49258501} is a Dioxin & Furan analysis of the pending registration source.

Note - There are two R351 actions on 35935-38 and an addition non-PRIA guided action to add 3 additional sources on 35935-38. This study is for the source that was submitted on August 13, 2013 [redacted]

Regards,

Matt

Matthew Granahan
Regulatory Manager
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Phone: (708) 377-1330 (main)
Phone: (708) 377-1421 (direct)
Phone: [redacted] (cell)
Fax: (708) 377-1425 (regulatory dept.)
Email: matthew.granahan@us.nufarm.com

Personal privacy information

- 49258501.035935-00038.Technical Dicamba (NUP-13010).20131003.Dioxin Furan.pdf

Product ingredient source information may be entitled to confidential treatment

E-SUBMISSION

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 19, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-482084
EPA File Symbol or Registration Number: 35935-38
Product Name: DICMBA ACID TECHNICAL
EPA Receipt Date: 15-Aug-2013
EPA Company Number: 35935
Company Name: NUFARM LIMITED

MATTHEW GRANAHAN
NUFARM AMERICAS INC.
11901 SOUTH AUSTIN AVENUE
ALSIP, IL 60803

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

E-SUBMISSION

35985-38

E-SUBMISSION

Memorandum

Date: 08 / 19 / 13

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 9-5-13

Document Part Of: 35935-38
MRID, If Any: 491904

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

STEPHEN SCHAIBLE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 19, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 15-AUG-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Nufarm Limited
4020 Aerial Center Parkway
Suite 101
Morrisville, NC 27560

TRANSMITTAL DOC FOR Dicamba Acid Technical (35935-38)
August 13, 2013

Vol. No.	OPPTS No.	Study References	MRID No.
1	N/A	**Administrative Documents**	49190400
2	830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800	Technical Dicamba, NUP-13010 Product Identity and Process, OPPTS Sections 830.1550, 830.1600, 860.1620, 830.1670, 830.1700, 830.1750, 830.1800 Unpublished study by Nufarm Americas Inc. Study No. RTP-13-052-REG. 87 pages Total	49190401
3	830.1700	Dicamba Acid Technical (NUP-13010) Preliminary Analysis, OPPTS Section 830.1700. Unpublished study by Nufarm Americas Inc. Study No. 36537. 77 pages Total	49190402
4	830.6302, 830.6303, 830.6304, 830.7000, 830.7050, 830.7200 830.7300	Dicamba Acid Technical (NUP-13010) Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Density/Bulk Density, UV/Visible Absorption, and Melting Point, OPPTS Sections 830.6302, 830.6303, 830.6304, 830.7000, 830.7050, 830.7200, 830.7300 Unpublished study by Nufarm Americas Inc. Study No. 36538. 18 pages Total	49190403

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

August 13, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R351 action, adding a new unregistered source of active ingredient. It is our opinion that this action falls under category R351, amendment adding a new unregistered source of active ingredient and as such the PRIA fee of $11,996.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate an 8 month + 21 day review period by the Agency on this submission.

This new, submitted, unregistered source of active ingredient falls within the certified limits of the existing Basic CSF for this registration.

In addition to the additional source of AI, Nufarm has added an additional crop to the label – Teff. The enclosed data matrix is a cite-all for Dicamba registrants and as such should cover the added use of Teff, which is found on [redacted] For ease of reference a highlighted copy of the label has been included with this submission.

To process this request please find attached e-submission which includes the studies, revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

Product ingredient source information may be entitled to confidential treatment

~ 23

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 8/15/13

Experts In-Processing Signature: MP Date 8/19 Fee Paid: Yes ←

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 35935-38	EPA Receipt Date: 8/15/13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes**	**no**			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments: Studies passed 11-3 review. Pass 4/9/04.

Technical & Impurities only, no inerts to review

8/21/13 - An e-mail was sent to the registrant regarding the Certification form, which had a deficiency.

- Received corrected form.

IV

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Jackson, Tracy

From: Jackson, Tracy
Sent: Wednesday, August 21, 2013 7:59 AM
To: 'matthew.granahan@us.nufarm.com'
Subject: Application deficiency (35935-38)

Dear Mr. Granahan,

I am contacting you regarding your submission in support of **Dicamba Acid Technical (35935-38)**. On the Certification with Respect of Citation of Data form (EPA Form 8570-34), under Section I: Method of data support, the box on the right hand side should be checked. This is the one that states "I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Please send corrected form to **jackson.tracy@epa.gov**

Thank you

Tracy Jackson
EPA Contractor
703-308-7227
2777 S. Crystal Drive
Arlington, VA 22202

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 19, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-482084
EPA File Symbol or Registration Number: 35935-38
Product Name: DICMBA ACID TECHNICAL
EPA Receipt Date: 15-Aug-2013
EPA Company Number: 35935
Company Name: NUFARM LIMITED

MATTHEW GRANAHAN
NUFARM AMERICAS INC.
11901 SOUTH AUSTIN AVENUE
ALSIP, IL 60803

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{939800ì~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 23

Receipt No. S- 939800

EPA File Symbol/Reg. No. 35935-38

Pin-Punch Date: 8/15/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R351

Granted: R351

Amount Due: $ 11,996.00

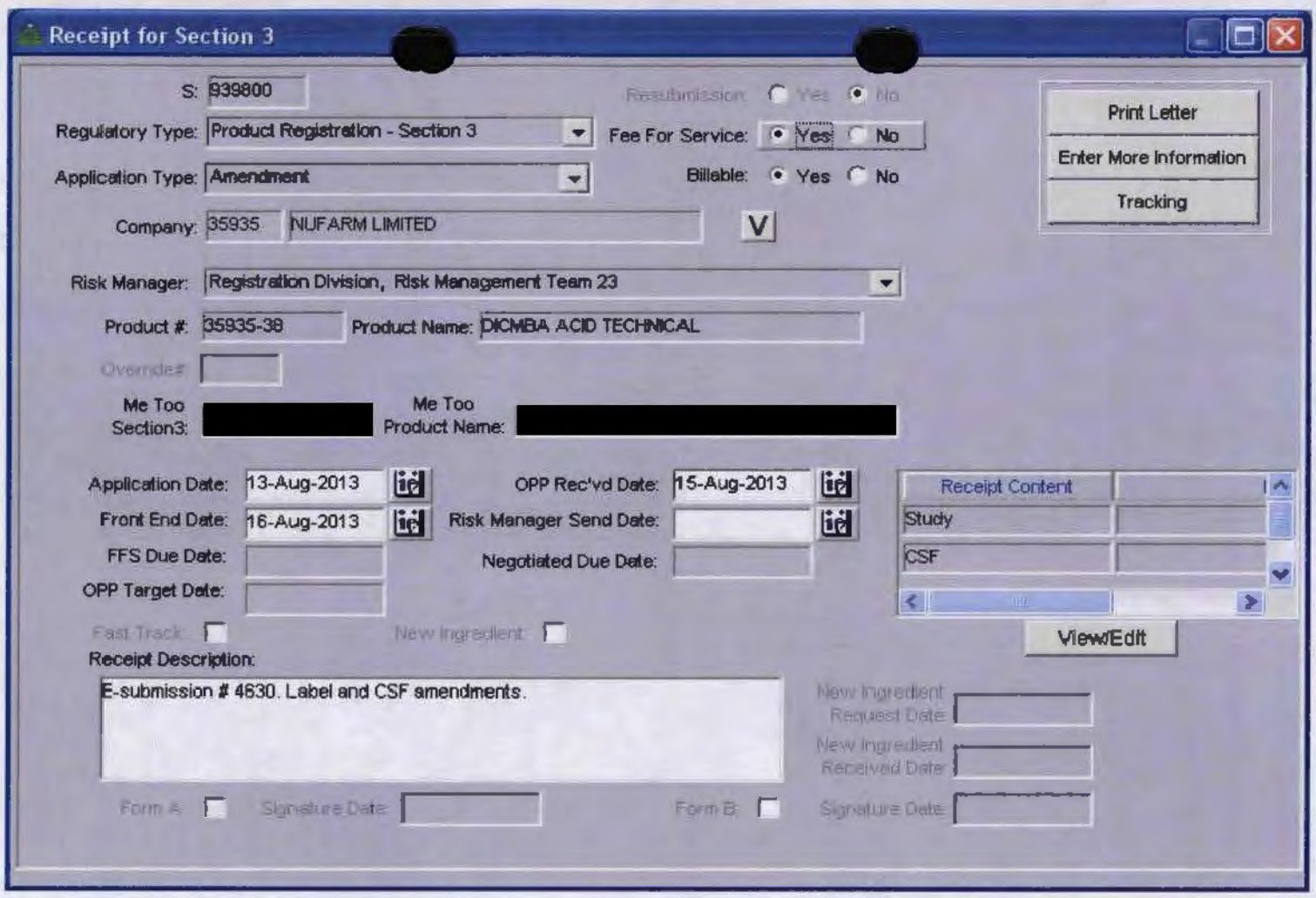
Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: [signature] Date: 8/19/13

Remarks:

E-SUBMISSION



Product ingredient source information may be entitled to confidential treatment

E-SUBMISSION

[redacted] [redacted]

Pay.gov Payment Confirmation : PRIA Service Fees
paygovadmin to: matthew.granahan@us.nufarm.com 08/14/2013 09:26 AM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25BVDECH
Agency Tracking ID: 74490231187
Transaction Type: Sale
Transaction Date: Aug 14, 2013 10:25:06 AM

Account Holder Name: Matthew Granahan
Transaction Amount: $11,996.00
Billing Address: 11901 S. Austin Ave.
City: Alsip
State/Province: IL
Zip/Postal Code: 60803
Country: USA
Card Type: MasterCard
Card Number: **********6875

Decision Number:
Registration Number: 35935-38
Company Name: Nufarm Limited
Company Number: 35935
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

E-SUBMISSION

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

August 13, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R351 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R351 action, adding a new unregistered source of active ingredient. It is our opinion that this action falls under category R351, amendment adding a new unregistered source of active ingredient and as such the PRIA fee of $11,996.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate an 8 month + 21 day review period by the Agency on this submission.

This new, submitted, unregistered source of active ingredient falls within the certified limits of the existing Basic CSF for this registration.

In addition to the additional source of AI, Nufarm has added an additional crop to the label – Teff. The enclosed data matrix is a cite-all for Dicamba registrants and as such should cover the added use of Teff, which is found on [redacted] For ease of reference a highlighted copy of the label has been included with this submission.

To process this request please find attached e-submission which includes the studies, revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

E-SUBMISSION

Product ingredient source information may be entitled to confidential treatment

Nufarm Limited
4020 Aerial Center Parkway
Suite 101
Morrisville, NC 27560

Vol. No.	OPPTS No.	Study References	MRID No.
1	N/A	**Administrative Documents**	49190400
2	830.1550, 830.1600, 830.1620, 830.1670, 830.1700, 830.1750, 830.1800	Technical Dicamba, NUP-13010 Product Identity and Process, OPPTS Sections 830.1550, 830.1600, 860.1620, 830.1670, 830.1700, 830.1750, 830.1800 Unpublished study by Nufarm Americas Inc. Study No. RTP-13-052-REG. 87 pages Total	49190401
3	830.1700	Dicamba Acid Technical (NUP-13010) Preliminary Analysis, OPPTS Section 830.1700. Unpublished study by Nufarm Americas Inc. Study No. 36537. 77 pages Total	49190402
4	830.6302, 830.6303, 830.6304, 830.7000, 830.7050, 830.7200 830.7300	Dicamba Acid Technical (NUP-13010) Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Density/Bulk Density, UV/Visible Absorption, and Melting Point, OPPTS Sections 830.6302, 830.6303, 830.6304, 830.7000, 830.7050, 830.7200, 830.7300 Unpublished study by Nufarm Americas Inc. Study No. 36538. 18 pages Total	49190403

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathryn Montague	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: 100-905, 33658-12, 35935-38, [redacted] 7969-132,
EPA Reg. No. 80967-8, 83520-8, 9468-45
Product Name Dicamba Technical Registrations

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

R351 - Amendment adding a new unregistered source of AI
$11,996
8 month review

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	50 - 250 lbs, bulk	[X]

6. Manner in Which Label is Affixed to Product [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other Self-Adhesive Integrated Label/Booklet

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Granahan	Regulatory Manager	(708) 377-1421

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
[signature]	Regulatory Manager	Matthew Granahan matthew.granahan@us.nufarm.com	08/13/2013

E-SUBMISSION

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 (708) 377-1421	35935-38
Active Ingredient(s) and/or representative test compound(s) Dicamba (3,6-dichloro-o-anisic acid)	Date 08/21/2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Crop, Terrestrial Feed Crop, Terrestrial Nonfood Crop, Forestry, Aquatic Noncrop, Domestic Outdoor	Product Name Dicamba Acid Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

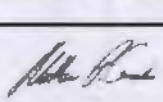
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	08/21/2013	Matthew Granahan Regulatory Manager

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560 (708) 377-1421	35935-38
Active Ingredient(s) and/or representative test compound(s) Dicamba (3,6-dichloro-o-anisic acid)	Date 08/13/2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Crop, Terrestrial Feed Crop, Terrestrial Nonfood Crop, Forestry, Aquatic Noncrop, Domestic Outdoor	Product Name Dicamba Acid Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

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I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Matthew Granahan	08/13/2013	Matthew Granahan Regulatory Manager

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 1 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS Series 830	**Product Properties**				
830.1550	Product identity and composition	49190401	Nufarm Americas Inc.	Own	
830.1600	Description of materials used to produce the product	49190401	Nufarm Americas Inc.	Own	
830.1620	Description of production process	49190401	Nufarm Americas Inc.	Own	
830.1650	Description of formulation process				1
830.1670	Discussion of formation of impurities	49190401	Nufarm Americas Inc.	Own	
830.1700	Preliminary analysis	49190401, 49190402	Nufarm Americas Inc.	Own	
830.1750	Certified limits	49190401	Nufarm Americas Inc.	Own	
830.1800	Enforcement analytical method	49190401	Nufarm Americas Inc.	Own	
830.1900	Submittal of sample				2
830.6302	Color	49190403	Nufarm Americas Inc.	Own	
830.6303	Physical state	49190403	Nufarm Americas Inc.	Own	
830.6304	Odor	49190403	Nufarm Americas Inc.	Own	
Signature		Name and Title Matthew Granahan, Regulatory Manager		Date 08/13/2013	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 2 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	47074503	Nufarm Americas Inc.	Own	
830.6314	Oxidation/reduction: chemical incompatibility	47267101	Nufarm Americas Inc.	Own	
830.6315	Flammability				3
830.6316	Explodability				4
830.6317	Storage stability	Being Undertaken	Nufarm Americas Inc.	Own	
830.6319	Miscibility				5
830.6320	Corrosion characteristics	Being Undertaken	Nufarm Americas Inc.	Own	
830.6321	Dielectric breakdown voltage				6
830.7000	pH	49190403	Nufarm Americas Inc.	Own	
830.7050	UV/Visible absorption	49190403	Nufarm Americas Inc.	Own	
830.7100	Viscosity				7
830.7200	Melting point/melting range	49190403	Nufarm Americas Inc.	Own	
830.7220	Boiling point/boiling range				8
830.7300	Density/relative density/bulk density	49190403	Nufarm Americas Inc.	Own	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 3 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation constants in water	47074503	Nufarm Americas Inc.	Own	
830.7520	Particle size, fiber length, and diameter distribution				9
830.7550	Partition coefficient (n-octanol/water), shake flask method	47074503	Nufarm Americas Inc.	Own	
830.7560	Partition coefficient (n-octanol/water), generator column method				10
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography				11
830.7840	Water solubility: column elution method; shake flask method	47074503	Nufarm Americas Inc.	Own	
830.7860	Water solubility: generator column method				12
830.7950	Vapor pressure	47074504	Nufarm Americas Inc.	Own	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 4 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
40 CFR 158.340	**Toxicology**				
870.1100	Acute oral toxicity - rat	Cite-all	-	PAY	
870.1200	Acute dermal toxicity - rat	Cite-all	-	PAY	
870.1300	Acute inhalation toxicity - rat	Cite-all	-	PAY	
870.2400	Primary eye irritation - rabbit	Cite-all	-	PAY	
870.2500	Primary dermal irritation -rabbit	Cite-all	-	PAY	
870.2600	Dermal sensitization - Guinea pig	Cite-all	-	PAY	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 5 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements					
Nufarm Limited made offers-to-pay to the following companies on the data submitters list of April 8, 2013					
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Syngenta Crop Protection, LLC (100)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Americas Inc. (228)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		The Scotts Company (239)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		BASF Corporation (241)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		E. I. DuPont De Nemours and Company (352)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Bayer Environmental Science (432)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Monsanto Company (524)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Scotts Company, The (538)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Lebanon Seaboard Corporation (961)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		PBI/Gordon Corp (2217)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		BASF Corporation (7969)	PAY	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 6 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		The Andersons Lawn Fertilizer Division (9198)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Ritter Chemical, LLC (9468)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Chemsico (9688)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Loveland Products, Inc. (34704)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Limited (35935)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Albaugh Inc (42750)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Dow AgroSciences LLC (62719)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Spray Drift Task Force (66607)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Repar Corp (69361)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Petro-Canada Lubricants Inc., A Suncor (69526)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Gharda USA, Inc. (70907)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Nufarm Inc. (71368)	OWN	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 7 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Outdoor Residential Exposure Task Force (71754)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agricultural Reentry Task Force (71755)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Bayer Advanced (72155)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Swiss Farms Products (73327)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		FIFRA Endangered Species Task Force (73989)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Residential Exposure Joint Venture (74888)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agricultural Handler Exposure Task Force (75234)	OWN	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Mey Corporation (80967)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Libertas Now, Inc. (81442)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Direct Ag Source, LLC (8322)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Tacoma Ag, LLC (83520)	PAY	
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Gharda Generics, Inc (84836)	PAY	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 8 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Dicamba Requirements	Cite-All Method utilized by Nufarm Limited for Dicamba data requirements.		Agrium Advanced Technologies (U.S.) Inc (84886)	PAY	

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DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 9 of 9
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

EXPLANATORY NOTES

Note #	Guideline Ref. #	Name of Test	Comment
1	830.1650	Description of formulation process	Not applicable to TGAI product. Guideline 830.1620 is primary.
2	830.1900	Submittal of samples	Not applicable unless specifically requested by the Agency.
3	830.6315	Flammability	Not applicable to TGAI.
4	830.6316	Explodability	Not applicable to TGAI.
5	830.6319	Miscibility	Not applicable to TGAI.
6	830.6321	Dielectric breakdown voltage	Not applicable to TGAI.
7	830.7100	Viscosity	Not applicable to TGAI.
8	830.7220	Boiling point/boiling range	Not applicable because product is not a liquid.
9	830.7520	Particle size, fiber length, and diameter distribution	Not applicable because product is not fibrous.
10	830.7560	Partition coefficient (n-octanol/water), generator column method	Addressed under 830.7840
11	830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	Addressed under 830.7840
12	830.7860	Water solubility: generator column method	Addressed under 830.7840

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DATA MATRIX

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Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560		Product Dicamba Acid Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
				Own	
				Own	
				Own	
					1
				Own	
				Own	
				Own	
				Own	
					2
				Own	
				Own	
				Own	

Signature	Name and Title Matthew Granahan, Regulatory Manager	Date 08/13/2013

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Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 2 of 3
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Own	
				Own	
					3
					4
				Own	
					5
				Own	
					6
				Own	
				Own	
					7
				Own	
					8
				Own	

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

DATA MATRIX

Date: August 13, 2013	EPA Reg. No./File Symbol 35935-38	Page 3 of 3
Applicant's/Registrant's Name & Address Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	Product Dicamba Acid Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Own	
					9
				Own	
					10
					11
				Own	
					12
				Own	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	
				PAY	

Material Sent for Data Extraction

Reg # 35935-38

Description: Amended Label

Material(s) Sent to Data Extraction Contractors:

- [x] New Stamped Label Dated 3/25/14
- [ ] Notification Dated _____
- [ ] New CSF(s) Dated _____
- [ ] Other: _____

Decision #: _____

Other Action/Comments: _____

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Kathryn Montague

Phone: (703)305-0123 Division: RD/PM Team 23

Date: _____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MAR 25 2014

Nufarm Ltd.
4020 Aerial Center Parkway
Morrisville, NC 27560

Subject: Label Amendment: Correcting omissions from 1/14/14 accepted label to include Agency-required revisions from 7/29/10 label accepted with comments.
EPA Reg. No.: 35935-38
Dicamba Acid Technical

Dear Mr. Granahan,

The Agency has received your application for an amendment, dated March 7, 2014. The label for the product described above, submitted under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved.

You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. If you have any questions, please contact Kathryn Montague (703-305-1243 or montague.kathryn@epa.gov).

Sincerely,

Kathryn V. Montague
Product Manager 23
Herbicide Branch
Registration Division (7505P)

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid).	98.0%
OTHER INGREDIENTS:.	2.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 35935-38
EPA EST. NO.

MANUFACTURED FOR
NUFARM LIMITED
4020 AERIAL CENTER PARKWAY
MORRISVILLE, NC 27560

Nufarm

NET WEIGHT LBS. (KG)

035935-00038.20140310.Amendment

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes on skin or on clothing. Avoid contact with skin. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact (877) 325-1840 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage. For eye irritation, examination by an ophthalmologist may be initiated.	

ENVIRONMENTAL HAZARDS

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For The Following Uses:
(1) Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf, and sod farms;
(2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
(3) Uses for experimental purposes that are in compliance with U.S.EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment or mixing equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV031014)

LABEL HISTORY

FILE NAME	RV DATE	Comments
035935-00038.20100218.MASTER	RV021810	EPA SAL
035935-00038.20130813.Amendment	RV081313	Amendment
035935-00038.20130816.Amendment	RV081613	Amendment
035935-00038.20140114.MASTER	RV011414	EPA SAL
035935-00038.20140310.Amendment	RV031014	EPA Amendment

Montague, Kathryn V.

From: Star, David
Sent: Friday, March 14, 2014 1:01 PM
To: nathan.ehresman@us.nufarm.com
Cc: Dunn, Meghan; Montague, Kathryn V.
Subject: RE: EPA Notices of Arrival for entries 231-8011985-5 and 231-8011982-2

Importance: High

Dear Mr. Ehresman:

There are a number of new concerns and issues that EPA Region 5 has with the importation of the pesticide - 35935-38 – by Nufarm Americas, Inc.

1. The fact that the EPA-accepted label of January 14, 2014, though stamped accepted by the Office of Pesticide Programs, may in fact not actually comply with all previous directives made by the Product Manager, OPP/EPA regarding past labeling amendments to this registration, dating back to July 2010
2. The fact that Nufarm Americas, Inc. may be using an illegitimate source that has not been accepted under a formal amendment to this registration and its confidential statement of formula

Until Nufarm Americas, Inc. can clearly demonstrate that they have properly complied with all directives of the Product Manager for an acceptable label in connection with past amendments to 35935-38, and can clearly demonstrate that the primary or alternate confidential statements of formula associated with 35935-38 have been reviewed and accepted by the Agency for the producing establishment from which this import shipment was manufactured, packaged and labeled, Region 5 will continue to place this entry under an enforcement hold with the U.S. Customs and Border Protection.

David Star
Chief, Pesticides & Toxics Compliance Section
Chemicals Management Branch
U.S. EPA Region 5 - Chicago
312-886-6009 (telephone)
312-692-2536 (facsimile)
EPA United States Environmental Protection Agency

From: nathan.ehresman@us.nufarm.com [mailto:nathan.ehresman@us.nufarm.com]
Sent: Friday, March 14, 2014 9:23 AM
To: Dunn, Meghan; Star, David
Subject: Fw: EPA Notices of Arrival for entries 231-8011985-5 and 231-8011982-2

Meghan-

I have been attempting to reach you & David Star. I would like to have a conference call today with you & David to discuss the hold on the Nufarm entry 231-8011985-5. I am free anytime.

We discussed the label on our call Wednesday, The Nufarm labeling on this shipment complies with the EPA stamped accepted label dated January 14, 2014. EPA region 5 has not informed me of any discrepancy vs. the EPA accepted label. I need clear communication from Region 5 on the reason for the hold and the statutory basis for this decision.

As I indicated, on forthcoming shipments, we are willing to fully cooperate, make any label modifications EPA HQ de
necessary, and will do so in an expeditious manner.

Thank you.

Nathan P. Ehresman
Director, Regulatory Affairs
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
Phone: 919.379.2515
Mobile: [redacted]
nathan.ehresman@us.nufarm.com

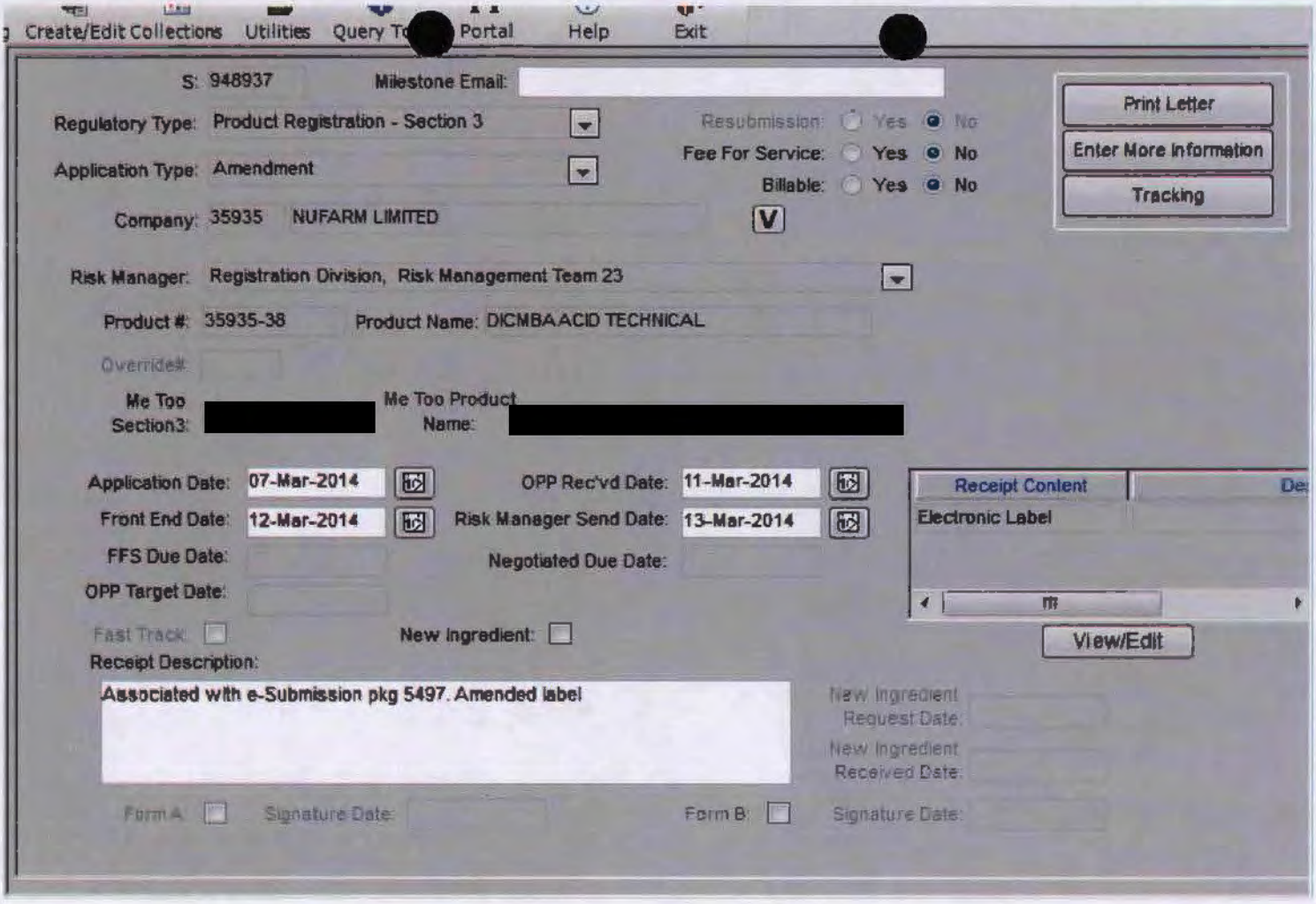
Personal privacy information

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: RBaris Date: 3/13/14 PM #: 23

EPA Reg. Number: 35935-38	EPA Receipt Date: 3/11/14

1	**Application Form** (EPA Form 8570-1) - signed?	✓		
2	**Confidential Statement of Formula** (EPA Form 8570-29) - signed?			—
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) - signed?	✓		
4	**Formulator's Exemption Statement** (EPA Form 8570-27) - signed?			✓
5	**Data Matrix** (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			✓
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	**Is Label included?** (5 copies)	✓		
	a) Electronic Label submitted?	✓		
	Comments:			



Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 13, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

NATHAN P. EHRESMAN
NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560-

PRODUCT NAME: DICMBA ACID TECHNICAL
COMPANY NAME: NUFARM LIMITED
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 35935-38
EPA RECEIPT DATE: 03/11/14

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{948937Z~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 23

Receipt No. S-	948937
EPA File Symbol/Reg. No.	35935-38
Pin-Punch Date:	3/11/2014

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Steve Schaible Date: 3/13/14

Remarks:

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

March 7, 2014

Kathryn Montague (PM-23)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Fast Track Non-PRIA Guided Label Amendment – per Region 5

Dear Ms. Montague:

Nufarm Limited is submitting a Non-PRIA Guided label Amendment for Dicamba Acid Technical, EPA Reg. No. 35935-38. On March 7, 2014 Meghan Dunn (US EPA Region 5) communicated to Nufarm the possibility the container label matching the recent EPA Stamped Accepted Label for this registration (dated January 14, 2014), as being misbranded. The recently accepted January 14, 2014 EPA Stamped Accepted Label did not incorporate the EPA comments on the July 29, 2010 reregistration for Dicamba. The attached label has incorporated those comments.

The change in the name of the AI, as requested in the comments on the EPA SAL dated February 18, 2010 [from: "Dicamba (3,6-dichloro-o-anisic acid)" to "3,6-dichloro-2-methoxybenzoic acid)"], has not been incorporated into the label. Justification for this lack of change is due to the naming of the AI "Dicamba (3,6-dichloro-o-anisic acid)" being accepted through the reregistration of the product and several other registrants have the identical name for Dicamba on their EPA Accepted Technical labels [to name a few EPA Reg. Nos. 33658-12, 42750-57 and 7969-132].

Nufarm kindly requests an expedited review of the amended label as we require this change to be accepted by the EPA to allow for importation. To process this request please find revised labelling, EPA forms, and copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [X] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathryn Montague	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [X] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Non-PRIA Guided Fast Track Label Amendment - per Meghan Dunn EPA Region 5.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	50 - 250 lbs, bulk	[X]

6. Manner in Which Label is Affixed to Product [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other Self-Adhesive Integrated Label/Booklet

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Granahan	Regulatory Manager	(708) 377-1421

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Matthew Granahan	Regulatory Manager
4. Typed Name Matthew Granahan matthew.granahan@us.nufarm.com	**5. Date** 03/07/2014

E-SUBMISSION

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	**Date Submitted to EPA**	**Electronic file name**
35935-38	03/07/2014	035935-00038.20140307.Amendment

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

03/07/2014

Date

Matthew Granahan

Name (typed)

Regulatory Manager

Title

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JAN 14 2014

Matthew Granahan
Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803

Dear Mr. Granahan:

SUBJECT: Alternate Confidential Statement of Formula (CSF) and
Label Amendment
EPA Registration No. 35935-38
Your Submission Dated August 16, 2013
Decision #482931

The Agency has reviewed the proposed alternate CSF, dated August 16, 2013, and has determined it to be acceptable. A copy will be placed in your files as part of the record. A copy of the review is enclosed. The label amendment referred to above, submitted in accordance with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Please submit one (1) copy of your final printed labeling before you release the product for shipment. This amended labeling supersedes all previously accepted ones.

Sincerely yours,

Kathryn V. Montague
Product Manager (23)
Herbicide Branch
Registration Division (7505P)

Enclosure

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid).	98.0%
OTHER INGREDIENTS:.	2.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 35935-38
EPA EST. NO.

MANUFACTURED FOR
NUFARM LIMITED
4020 AERIAL CENTER PARKWAY
SUITE 101
MORRISVILLE, NC 27560

Nufarm

NET WEIGHT LBS. (KG)

035935-00038.20130813.Amendment

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IF SWALLOWED. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact (877) 325-1840 for emergency medical treatment information.	
NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.	

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds. Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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(1) Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, teff, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf, and sod farms;
(2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
(3) Uses for experimental purposes that are in compliance with U.S.EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment or mixing equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BYWAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV081313)

LABEL HISTORY

FILE NAME	RV DATE	Comments
035935-00038.20100218.MASTER	RV021810	EPA SAL
035935-00038.20130813.Amendment	RV081313	New

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathryn Montague	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*
Nufarm Limited
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. [redacted]
Product Name [redacted]

Section - II

[X] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[X] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

R300 - Amendment adding a 100% repack TGAI source.
$1,434.00 PRIA Fee
4 month review

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [X] Other (Specify) HDPE
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [X] Container	50 - 250 lbs, bulk	[X]

6. Manner in Which Label is Affixed to Product [X] Lithograph [X] Paper glued [ ] Stenciled [ ] Other Self-Adhesive Integrated Label/Booklet

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Granahan	Regulatory Manager	(708) 377-1421

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
[signature]	Regulatory Manager	
4. Typed Name	**5. Date**	
Matthew Granahan matthew.granahan@us.nufarm.com	08/16/2013	E-SUBMISSION

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

Nufarm Americas Inc.
11901 South Austin Avenue
Alsip, IL 60803
Telephone: (708) 377.1330 Facsimile: (708) 377.1333
www.us.nufarm.com

August 16, 2013

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Subject: **Dicamba Acid Technical**
EPA Reg. No. 35935-38
Non-Fast track PRIA Guided R300 Submission

Dear Ms. Montague:

By way of this submission Nufarm Limited is submitting a PRIA Guided R300 action, adding a registered source of active ingredient, which is a 100% repack. It is our opinion that this action falls under category R300, and as such the PRIA fee of $1,434.00 has been prepaid and a copy of evidence of the payment has been included in this submission. We anticipate a 4 month + 21 day review period by the Agency on this submission.

Please note on August 13, 2013 Nufarm Limited submitted CSF Alt 1 as an R351 action, this action is currently pending at the Agency. The CSF submitted on this 100% repack TGAI source is CSF Alt 2.

On this submitted label (as well as the label submitted August 13, 2013) Nufarm has added Teff to the label. Small grains, of which Teff is grouped under, are already on the accepted label. For ease of reference a highlighted copy of the label has been included with this submission. With this addition of Teff the submitted label matches for which a 100% repack source is being submitted.

To process this request please find attached e-submission which includes the revised labelling, CSF, EPA forms, PRIA Payment, copy of this cover letter needed to support this registration request.

If you should have any questions regarding this matter, feel free to contact me at (708) 377-1421 or email at matthew.granahan@us.nufarm.com.

Thank you,

Matthew Granahan
Regulatory Manager
Nufarm Limited

E-SUBMISSION

ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: November 17, 2013 **Action Code**: 345
DP BARCODE No.: 415153 **REG. No.**: 35935-38 **Decision No**: 482931
Company Name: Nufarm Limited
Manufacturing-Use Product: "Dicamba Acid Technical"
PC Code(s): 029801

FROM: William Herald / Microbiologist (MS) / Chemist, REHS / Registered Sanitarian
Product Chemistry Team
Technical Review Branch/RD (7505P)

TO: Dianne Morgan / Kathryn Montague, RM 23
Herbicide Branch / RD (7505P)

INTORDUCTION:

The registrant has submitted a CSF for an alternate formulation No. 2 (dated 8/16/13) to support the registration of the manufacturing- use product, "Dicamba Acid Technical". The proposed alternate formulation depends from approved Basic CSF (dated 3/7/07) EPA Reg. No. 35935-38; and Alt. No. 2 CSF is a 100% repack of EPA Reg. No [redacted] which has the same CAS No for the active ingredient as the Basic CSF [EPA Reg. No. 36035-38]for the active ingredient.. TRB has been asked to evaluate the alternate No. 2 CSF (dated 8/16/13) formulation and determine its acceptability.

SUMMARY OF FINDINGS

1. Said proposed Alt. No. 2 CSF is a 100% repack of [redacted] [EPA Reg. No. [redacted]

2. The proposed Alt. No. 2 CSF (dated 8/16/13) is an alternate CSF dependent from the Basic CSF (dated 3/7/07) Reg. No. 35935-38; but is a 100% repack of EPA Reg. No. [redacted] which has the same CAS number as the Basic CSF [EPA Reg. No. 35935-38]. It is noted that the Basic CSF has listed only [redacted] impurities whereas the source of the 100% repack has listed [redacted] impurities in the Basic CSF for EPA Reg. No. [redacted]

3. Both the Basic CSFs, Reg. No. 35935-38 and Reg. No. [redacted] are substantially similar in chemical composition and physical-chemical properties.

4. There are no inert ingredients in the product.

CONCLUSION:

The TRB has reviewed the proposed alternate CSF No. 2 (dated 8/16/13) and has determined it to be acceptable.

Product ingredient source information may be entitled to confidential treatment

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid)	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

EPA REG. NO. 35935-38
EPA EST. NO.

MANUFACTURED FOR
NUFARM LIMITED
4020 AERIAL CENTER PARKWAY
SUITE 101
MORRISVILLE, NC 27560

Nufarm

NET WEIGHT LBS. (KG)

035935-00038.20130816.Amendment

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

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If you do not agree with or do not accept any of the directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV081613)

Form approved. OMB No. 2070-0060, 2070-0057, 207[redacted]07, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Nufarm Limited 4020 Aerial Center Parkway, Suite 101 Morrisville, NC 27560	35935-38
	Product Name Dicamba Acid Technical
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 02/27/2007 (live formulation - accepted), 08/13/2013 (live formulation - pending), 08/16/2013 (100% repack formulation - submitted)

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Dicamba (3,6-dichloro-o-anisic acid)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Dicamba (3,6-dichloro-o-anisic acid)	[redacted]	[redacted]

Product ingredient source information may be entitled to confidential treatment

Signature	Name and Title	Date
[signature]	Matthew Granahan Regulatory Manager	08/16/2013

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

E-SUBMISSION

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	**Date Submitted to EPA**	**Electronic file name**
35935-38	08/16/2013	035935-00038.20130816.Amendment

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

08/16/2013

Date

Matthew Granahan

Name (typed)

Regulatory Manager

Title

E-SUBMISSION

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 23, 2013

OFFICE OF CHEMICAL
SAFETY
AND POLLUTION
PREVENTION

NATHAN P. EHRESMAN
NUFARM LIMITED
NUFARM LIMITED
4020 AERIAL CENTER PKWY., STE 103
MORRISVILLE, NC 27560-

PRODUCT NAME: DICMBA ACID TECHNICAL
COMPANY NAME: NUFARM LIMITED
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 35935-38
EPA RECEIPT DATE: 08/20/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{939965^~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 23

Receipt No. S-	939965
EPA File Symbol/Reg. No.	35935-38
Pin-Punch Date:	8/19/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ~~R300~~

Granted: ~~R300~~

Amount Due: $ 1434

NO - FTA

9/3/13

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: [signature] Date: 8/23/13

Remarks: Needs Sim Clinic 100% re-pack.

E-SUBMISSION

Pay.gov Payment Confirmation : PRIA Service Fees
paygovadmin to: matthew.granahan@us.nufarm.com 08/16/2013 03:27 PM

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25C0G4CR
Agency Tracking ID: 74491367836
Transaction Type: Sale
Transaction Date: Aug 16, 2013 4:27:44 PM

Account Holder Name: Matthew Granahan
Transaction Amount: $1,434.00
Billing Address: 11901 S. Austin Ave.
City: Alsip
State/Province: IL
Zip/Postal Code: 60803
Country: USA
Card Type: MasterCard
Card Number: **********6875

Decision Number:
Registration Number: 35935-38
Company Name: Nufarm Limited
Company Number: 35935
Action Code: R300

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Nufarm Limited
George Meindl
Regulatory Affairs Manager
150 Harvester Drive, Suite 200
Burr Ridge, IL 60527
Phone: 630.455.2017 Fax: 630.455.2030
george.meindl@us.nufarm.com

August 6, 2010

Via Overnight Courier

Kathryn Montague (PM-23)
Document Processing Desk (FIN LABEL)
Office of Pesticide Programs (7505P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Dicamba Acid Technical
EPA Reg. No. 35935-38
Final Printed label

Dear Ms. Montague:

Enclosed are the subject product's final print labeling, which is now consistent with the EPA comment letter and EPA stamped label dated 7/29/2010.

To process this request please find enclosed the following:

- Application for Pesticide Registration (EPA form 8570-1)
- Final print labeling (1 copy)

If you should have any questions regarding this matter, please feel free to contact me at 630.455.2017 or email at george.meindl@us.nufarm.com.

Sincerely,

George Meindl
Regulatory Affairs Manager
Nufarm Limited

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
35935-38	Kathyrn Montague	☐ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Dicamba Acid Technical	23	

5. Name and Address of Applicant *(Include ZIP Code)*

Nufarm Limited
104 T.W. Alexander Drive (PO Box 13439)
RTP, NC 27709

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☒ Final printed labels in reponse to Agency letter dated 7/29/2010
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
George Meindl george.meindl@us.nufarm.com	Regulatory Affairs Manager	630.455.2017

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
	Regulatory Affairs Manager	George Meindl	8/6/2010

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:

Dicamba (3,6-dichloro-o-anisic acid)	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL	100.0%

EPA Reg. No. 35935-38 **EPA Est. No.** 082783-CHN-001

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid contact with skin. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. For eye irritation, examination by an ophthalmologist may be indicated.

ENVIRONMENTAL HAZARDS

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

STORAGE AND DISPOSAL *(continued)*

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV072910)

NET CONTENTS: 1,763.7 lbs. (800 Kg)

Manufactured for:
Nufarm Limited
P.O. Box 13439
RTP, NC 27709

Nufarm

Material to be added to an e-Jacket/Jacket

Reg. No. 35935-38

Description: Reregistered Product

1. ☒ Placement within the e-Jacket/jacket:
   - ☒ Default: (chronological, top = newest)
   - ☐ File Location: (PDF page number, i.e., "before page 45")

2. ☒ Send to Data Extraction contractors this material:
   - ☒ Newly stamped accepted label
   - ☐ Notification
   - ☒ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Hope Johnson

Phone: 305 5410 Division: RD/HB

Date: JUL 29 2010

Created August 14, 2008

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
35935-38	JUL 29 2010

Term of Issuance:

NOTICE OF PESTICIDE:
__ Registration
_X_ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:
Dicamba Acid Technical

Name and Address of Registrant (include ZIP Code):

Nufarm Limited
PO Box 13439
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is reregistered in accordance with FIFRA provided that you:

1. Submit and/or cite all data required for registration review/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. The Agency recommends that additional text be added to the Note to Physician that addresses eye irritation concerns and includes technical information on symptomatology, supportive treatments, etc.
3. Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read: "DANGER Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid contact with skin."
4. Move the IF ON SKIN OR CLOTHING First Aid Statement to before the IF SWALLOWED statement
5. Delete the text "Keep out of lakes, streams, or ponds" from the Environmental Hazards statements.
6. Revise the Disposal section per PRN 2007-4.

Submit one copy of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Contact Hope Johnson at 703-305-5410 if you have any questions.

Signature of Approving Official:	Date:
Kathryn Montague Product Manager 23 Herbicide Branch Registration Division (7505P)	JUL 29 2010

EPA Form 8570-6

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACCEPTED with COMMENTS In EPA Letter Dated: JUL 29 2010 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 35935-38

ACTIVE INGREDIENT:

Dicamba (3,6-dichloro-o-anisic acid)	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL	100.0%

EPA Reg. No. 35935-38 **EPA Est. No.** 082783-CHN-001

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IN SWALLOWED. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds. Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

STORAGE AND DISPOSAL *(continued)*

CONTAINER DISPOSAL: Plastic Bag: Completely empty bag into manufacturing equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARD TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

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If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV101107)

NET CONTENTS: 1,763.7 lbs. (800 Kg)

Manufactured for:
Nufarm Limited
P.O. Box 13439
RTP, NC 27709

Nufarm

DATE OUT: 03/APR/09

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [x]; MUP [x]; EUP [ ]
BARCODE NO.: D363565 **REG./FILE SYMBOL NO.:** 35935-38
PRODUCT NAME: Dicamba Technical **MRID NO.:** 472671-01
COMPANY NAME: Nufarm Limited **ACTION CODE:** 675

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508P)

TO: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

INTRODUCTION:

With this resubmission, ~~BASF Corporation~~ Nufarm Limited provided additional product chemistry data pertaining to the Oxidation/Reduction: Chemical Incompatibility of the product. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. **35935-38**.

FINDINGS:

1. EPA Reg. No. 35935-38 is a technical/manufacturing-use product that contains 98.0% Dicamba.

2. The Oxidation/Reduction: Chemical Incompatibility data presented in MRID number 472671-01 are acceptable and satisfy the requirements under 40 CFR 158.190 corresponding to GRN 830.6314. Results are listed in the table below:

Reactant	Minimum Temperature	Maximum Temperature
Blank	22°C	25°C
Water	223°C	24°C
Observations	The test substance and reactant formed a creamy beige paste. The mixture caked after 24 hours. There were no temperature effects.	
5 % Ammonium Phosphate	23°C	25°C
Observations	The test substance and reactant formed a creamy beige paste. The mixture caked after 24 hours. There were no temperature effects.	
Iron Powder	24°C	25°C
Observations	The test substance and reactant formed a homogeneous mixture. There were no significant changes or temperature effects over 24 hours.	
5% Potassium Permanganate	23°C	25°C
Observations	The test substance and reactant formed a dark purple paste. After 24 hours the mixture appeared as a shiny silver-brown caked powder. There were no temperature effects.	
Gasoline	23°C	24°C
Observations	The test substance did not disperse in the reactant. After 24 hours, the mixture appeared as a light reddish-beige caked powder. There were no temperature effects.	

3. In our previous review dated 3/25/09, the registrant was requested to submit the Preliminary Analysis and Dissociation Constant in Water data, in addition to Oxidation/Reduction: Chemical Incompatibility. These requirements were not addressed in this submission. ~~Guidelines~~ 80.6314, 830.7370, and 830.1700 are still outstanding.

4. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. There are no data present that trigger the Physical or Chemical Hazards statements on the label. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10 and PR Notice 83-3.

CONCLUSIONS:

Except for Finding 3, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **35935-38**.

DATE OUT: 25/MAR/09

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP []; EUP [x]
BARCODE NO.: D363281 **REG./FILE SYMBOL NO.:** 35935-38
PRODUCT NAME: Dicamba Technical **MRID NOS.:** 470745-01, -03, -04
COMPANY NAME: Nufarm Limited **ACTION CODE:** 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508P)

TO: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 0065, was issued in June, 2006 for the Technical Grade Active Ingredient (TGAI) Dicamba: 3,6-dichloro-2-methoxybenzoic acid. Compounds of Dicamba considered in the RED includes Dimethlyamine (DMA) salt, Sodium (Na) salt, Isopropylamine (IPA) salt, Diglycolamine (DGA) salt, and Potassium (K) salt. According to the RED, the generic data base supporting the reregistration of Dicamba have been reviewed and found to be substantially complete.

In the 8-month response to the Dicamba RED, ~~BASF Corporation~~ Nufarm Ltd. submitted a Confidential Statement of Formula (CSF) for the basic formulation, dated 3/6/09; a draft product label (no pin-punched date); and has referenced product chemistry data in MRID numbers 470745-01, -03, and -04. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. **35935-38**.

FINDINGS:

1. EPA Reg. No. 35935-38 is a technical/manufacturing-use product that contains 98.0% Dicamba.

2. The CSF for the basic formulation, dated 3/6/09, was filled out correctly and completely and is acceptable for reregistration of the subject product.

3. The data presented in MRID numbers 470745-01, -03, and -04 meet the product chemistry requirements as specified in 40 CFR§158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.330, 158.340, 158.350, and 158.355), which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method (Group A). The data also satisfy the requirements under 40CFR§158.190 (new 40 CFR section number is 158.310) which pertain to the Physical and Chemical properties of the product (Group B), except for Oxidation/Reduction: Chemical Incompatibility and Dissociation Constant in Water. The data were previously reviewed and accepted by the Technical Review Branch (TRB) of the Registration Division (RD) in connection with the registration of the subject product, on 8/16/07 under DP number 338483. PRB/SRRD concurs with RD's review and concludes that the data remain acceptable and will support reregistration of the subject product.

4. In addition to Oxidation/Reduction: Chemical Incompatibility and Dissociation Constant in Water, Preliminary Analysis was also cited as a data gap in the RD review for registration of the subject product. The registrant should be advised that these data are also outstanding for reregistration of the product. Guidelines 80.6314, 830.7370, and 830.1700 have not been satisfied.

5. Storage Stability and Corrosion Characteristics were waived for all Dicamba products during tbe Dicamba reregistration process, Case number 0065. No additional data are required.

6. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. There are no data present that trigger the Physical or Chemical Hazards statements on the label. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10 and PR Notice 83-3.

CONCLUSIONS:

Except for Finding 4, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **35935-38**.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 2, 2009

MEMORANDUM:

Subject: EPA Reg. No.: 35935-38/Dicamba Acid Technical
DP Barcode: 363559
Case No.: 0065

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Marianne Lewis 4/2/09

To: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Nufarm Ltd
P.O. Box 13439
104 T.W. Alexander Drive
Research Triangle Park, NC 27709

FORMULATION FROM EPA Reg. No. 35935-38 LABEL:

	% by wt.
Active Ingredient(s):	
Dicamba	98.0%
Inert Ingredient(s):	2.0%
Total	100.0%

BACKGROUND: In the 8 month response to the Dicamba RED, the registrant is citing the acute toxicity studies listed in the acute toxicity table for the technical in the RED to support the reregistration of their product, EPA Reg. No. 35935-38. The subject product is a technical. The technical acute toxicity values included in the RED are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

After reviewing the studies listed in the RED, the subject product will be assigned the following acute toxicity categories: acute oral (81-1) – III, acute dermal (81-2) – III, acute inhalation (81-3) – IV, primary eye irritation (81-4) – I, primary skin irritation (81-5) – II, and will be classified as a non sensitizer. The primary eye irritation study is reclassified as Toxicity Category I based on information contained in the study and in the open literature. If the registrant disagrees with this classification then a new study should be cited or submitted for review.

RECOMMENDATIONS:

- The subject product will be assigned the toxicity categories listed above.

The acute toxicity profile for EPA Reg. No. 35935-38 is currently:

Acute Oral	III	Cited (LD_{50} > 2740 mg/kg)
Acute Dermal	III	Cited (LD_{50} > 2000 mg/kg)
Acute Inhalation	IV	Cited (LC_{50} > 5.3 mg/L)
Primary Eye	I	Cited
Primary Dermal	II	Cited
Skin Sensitization	non sensitizer	Cited

NOTE: The acute toxicity study requirements have been satisfied for the subject product.

LABELING:

ID #: 035935-38 DICAMBA ACID TECHNICAL

SIGNAL WORD: **DANGER** **PELIGRO**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid contact with skin.

*The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category I and primary skin irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DATE OUT: 03/MAR/10

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [x]; MUP [x]; EUP [ ]
BARCODE NO.: D374508 **REG./FILE SYMBOL NO.:** 35935-38
PRODUCT NAME: Dicamba Technical **MRID NOS.:** 470745-02, -03
COMPANY NAME: Nufarm Limited **ACTION CODE:** 676

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
Risk Management and Implementation Branch V
Product Re-evaluation Division (7508P)

TO: Moana Appleyard, CRM
Risk Management and Implementation Branch V
Product Re-evaluation Division (7508P)

INTRODUCTION:

With this resubmission, Nufarm Limited provided additional product chemistry data pertaining to Preliminary Analysis (GRN 830.1700) and Dissociation Constant in Water (830.7370). The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. **35935-38.**

FINDINGS:

1. EPA Reg. No. 35935-38 is a technical/manufacturing-use product that contains 98.0% Dicamba.

2. Five batches of the Dicamba Acid Technical (NUP 06212) were analyzed for percent active ingredient and impurities present at 0.1% or greater to obtain a total accountability of 98% or greater. The study met the requirements of 40 CFR Part 160: US EPA (FIFRA) with the exception that characterization of the reference substance was not documented according to GLP. The analyses were conducted using a validated reverse phase HPLC analytical method. Impurities were analyzed using the same method and conditions. The operating conditions were included as well as sample calculations and chromatograms.

   Results:

Statement of Composition				
Test Substance Identification	Batch #	(Ave.) % Dicamba	% Impurities (Mean % Loss on Drying)	% Accountability
NUP 06212	20060746	99.99	0.15	100.14
	20060825	98.51	0.12	98.63
	20060821	98.86	0.18	99.04
	20060823	98.69	0.19	98.88
	20060826	99.08	0.13	99.21

No impurities were found in the active ingredient assay. Standards were run to insure that there was no interference with the active ingredient analysis based on retention time. Retention times for the impurities were not found to overlap that of the active ingredient.

The data presented (MRID number 470745-02) satisfy the requirements of 40 CFR 158.170, Preliminary Analysis.

THIS REVIEW CONTAINS FIFRA CBI

3. Information on Dissociation Constant in Water is presented in MRID number 470745-03. The statements are quoted as follows:

"During the preliminary Non-GLP method development, titration method was used to determine the pKa of dicamba. Due to the low pKa value of dicamba (literature reference as 1.96), no conclusive results were obtained, other than indication of pKa of less than 2. The titration method was not effective when the pH was less than 2.0.

The spectrophotomeric method was also employed to explore the possibility of dicamba pKa determination. Due to the extremely low solubility of the dicamba in aqueous solution, no meaningful spectra were obtained that would enable us to calculate the pKa value.

The conductometric method was not applicable because the low solubility of dicamba limited the ionic species presented in the solution."

Based on the preceding information, PRD/RMIB V will waive the Dissociation Constant requirement for the subject product. No additional data are required. GRN 830.1700 is now fulfilled.

4. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. There are no data present that trigger the Physical or Chemical Hazards statements on the label. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10 and PR Notice 83-3.

CONCLUSIONS:

The registrant has now satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **35935-38**.

Date: March 15, 2010

Reg. No.: 35935-38
Product Name: Dicamba Acid Technical
PM Name/Number: Kathryn Montague, Risk Management Team 23

Primary Reviewer: Judy Loranger Judy Loranger 4/13/10
Secondary Reviewer: Mark Perry MTP

New label or date of RD amended label: No pin-punch date on label, but states "(RV101107)"

Formulation Type: Technical

Active Ingredient Assessed: Dicamba/029801

Other ai's in product

Name/PC code:	Reregistration Status or Registration Date:
N/A	N/A

Note to PM:

1) The label states that this product can be used to formulate end use products for use on cotton. Per 40 CFR 180.227, it appears that a tolerance has been established for the use of dicamba on cotton (undelinted seed). The Risk Management and Implementation Branch V (RMIB V) defers to RD regarding the acceptability of the text on the label regarding this use.

Assessment can be found N:\prb\label\035935/038

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1) The Agency recommends that additional text be added to the Note to Physician that addresses eye irritation concerns.

2) Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

"DANGER
Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid contact with skin."

3) Delete the text "Keep out of lakes, streams, or ponds" from the Environmental Hazards statements.

Material to be added to an e-Jacket/Jacket

Reg. No. 35935-38

Description: Final Product Registration

1. ☒ **Placement within the e-Jacket/jacket:**
   - ☒ **Default: (chronological, top = newest)**
   - ☐ **File Location: (PDF page number, i.e., "before page 45")**

2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Moana Appleyard

Phone: 308-8175 **Division:** PRD

Date: 4/15/10

This form was created on 8/24/2009

PRODUCT REREGISTRATION

SUPPORTING DOCUMENTATION

FOR

Case Name: _____

Reg. No. _____

This supporting documentation (in chronological order) includes:

- Old labels (identified as "*Superceded by label dated xx/xx/xx)*
- Unacceptable CSF (marked "Not acceptable" and dated)
- Product chemistry reviews
- Acute toxicity reviews
- Efficacy and or special studies (if necessary)
- 90-Day responses to PDCI (forms A and B)
- Administrative forms (Application for Reregistration Certification to Data citation, Data Matrix)
- Correspondence (Company and Agency letters & e-mails)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 35935-38

2. EPA Product Manager: J. Stokes

3. Proposed Classification: [ ] None [ ] Restricted

4. Company/Product (Name): Dicamba Acid Technical

PM#: SRRD

5. Name and Address of Applicant *(Include ZIP Code)*

Nufarm Limited
P.O. Box 13439
RTP, NC 27709

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

8 month response to Dicamba RED DCI - no data submitted.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [x] Other (Specify) lined supersack
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 440 lb (200 kg)

5. Location of Label Directions: [X]

6. Manner in Which Label is Affixed to Product: [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
George Meindl (george.meindl@us.nufarm.com)	Regulatory Affairs Manager	630.455.2017

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingily false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: George Meindl

3. Title: Regulatory Affairs Manager

4. Typed Name: George Meindl

5. Date: 3/9/2009

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

In Section 13.K. of the protocol for test selection, the choice for Dissociation Constant was changed from 'Yes' to 'No' for the following reason: Preliminary NON-GLP method development indicated that the due to the extreme low solubility and extreme low pKa of the test material, neither titration nor conductometric methods can be used to assess the pKa value of the test material. Literature reference for the pKa value for Dicamba Technical is less than 2.0.

During the preliminary Non-GLP method development, titration method was used to determine the pKa of dicamba. Due to the low pKa value of dicamba (literature reference as 1.96), no conclusive results were obtained, other than indication of pKa of less than 2. The titration method was not effective when the pH was less than 2.0.

The spectrophotometric method was also employed to explore the possibility of dicamba pKa determination. Due to the extremely low solubility of the dicamba in aqueous solution, no meaningful spectra were obtained that would enable us to calculate the pKa value.

The conductometric method was not applicable because the low solubility of dicamba limited the ionic species presented in the solution.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 2, 2009

MEMORANDUM:

Subject: EPA Reg. No.: 35935-38/Dicamba Acid Technical
DP Barcode: 363559
Case No.: 0065

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

To: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Nufarm Ltd
P.O. Box 13439
104 T.W. Alexander Drive
Research Triangle Park, NC 27709

FORMULATION FROM EPA Reg. No. 35935-38 LABEL:

	% by wt.
Active Ingredient(s):	
Dicamba	98.0%
Inert Ingredient(s):	2.0%
Total	100.0%

BACKGROUND: In the 8 month response to the Dicamba RED, the registrant is citing the acute toxicity studies listed in the acute toxicity table for the technical in the RED to support the reregistration of their product, EPA Reg. No. 35935-38. The subject product is a technical. The technical acute toxicity values included in the RED are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

After reviewing the studies listed in the RED, the subject product will be assigned the following acute toxicity categories: acute oral (81-1) – III, acute dermal (81-2) – III, acute inhalation (81-3) – IV, primary eye irritation (81-4) – I, primary skin irritation (81-5) – II, and will be classified as a non sensitizer. The primary eye irritation study is reclassified as Toxicity Category I based on information contained in the study and in the open literature. If the registrant disagrees with this classification then a new study should be cited or submitted for review.

RECOMMENDATIONS:

- The subject product will be assigned the toxicity categories listed above.

The acute toxicity profile for EPA Reg. No. 35935-38 is currently:

Acute Oral	III	Cited (LD_{50} > 2740 mg/kg)
Acute Dermal	III	Cited (LD_{50} > 2000 mg/kg)
Acute Inhalation	IV	Cited (LC_{50} > 5.3 mg/L)
Primary Eye	I	Cited
Primary Dermal	II	Cited
Skin Sensitization	non sensitizer	Cited

NOTE: The acute toxicity study requirements have been satisfied for the subject product.

LABELING:

ID #: 035935-38 DICAMBA ACID TECHNICAL

SIGNAL WORD: **DANGER** **PELIGRO**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS*:

Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Avoid contact with skin.

*The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the primary eye irritation Toxicity Category I and primary skin irritation Toxicity Category II. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

DICAMBA ACID TECHNICAL

FOR MANUFACTURING PURPOSES ONLY

ACTIVE INGREDIENT:	
Dicamba (3,6-dichloro-o-anisic acid)	98.0%
OTHER INGREDIENTS:	2.0%
TOTAL	100.0%

EPA Reg. No. 35935-38 **EPA Est. No.** 082783-CHN-001

KEEP OUT OF REACH OF CHILDREN

DANGER

For Chemical Spill, Leak, Fire, or Exposure, Call CHEMTREC (800) 424-9300
For Medical Emergencies Only, Call (877) 325-1840

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. HARMFUL IN SWALLOWED. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
IF IN EYES	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-325-1840 for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds. Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This technical material may only be used to produce formulations that are registered or exempted from registration by the U.S. EPA. If it is desired to produce formulations that do not have prior approval, the producer of such formulations is responsible for providing all necessary data and for obtaining registration.

Only for Formulation Into A Herbicide For (1) The Following Use(s): asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms; (2) Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA regulations.

This product may be used to formulate products for specific uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

The user is solely responsible for determination of suitability of the use of this product for any specific purpose, any manufacturing practice employed, and adoption of such safety precautions as may be necessary.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in a well-ventilated area separately from fertilizer, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up and collected for disposal. Wash area of spill with detergent and water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

STORAGE AND DISPOSAL *(continued)*

CONTAINER DISPOSAL: Plastic Bag: Completely empty bag into manufacturing equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY DISCLAIMER

The directions for use of this product must be followed carefully. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, (1) THE GOODS DELIVERED TO YOU ARE FURNISHED "AS IS" BY MANUFACTURER OR SELLER AND (2) MANUFACTURER AND SELLER MAKE NO WARRANTIES, GUARANTEES, OR REPRESENTATIONS OF ANY KIND TO BUYER OR USER, EITHER EXPRESS OR IMPLIED, OR BY USAGE OF TRADE, STATUTORY OR OTHERWISE, WITH REGARO TO THE PRODUCT SOLD, INCLUDING, BUT NOT LIMITED TO, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USE, OR ELIGIBILITY OF THE PRODUCT FOR ANY PARTICULAR TRADE USAGE. UNINTENDED CONSEQUENCES, INCLUDING BUT NOT LIMITED TO INEFFECTIVENESS, MAY RESULT BECAUSE OF SUCH FACTORS AS THE PRESENCE OR ABSENCE OF OTHER MATERIALS USED IN COMBINATION WITH THE GOODS, OR THE MANNER OF USE OR APPLICATION, INCLUDING WEATHER, ALL OF WHICH ARE BEYOND THE CONTROL OF MANUFACTURER OR SELLER AND ASSUMED BY BUYER OR USER. THIS WRITING CONTAINS ALL OF THE REPRESENTATIONS AND AGREEMENTS BETWEEN BUYER, MANUFACTURER AND SELLER, AND NO PERSON OR AGENT OF MANUFACTURER OR SELLER HAS ANY AUTHORITY TO MAKE ANY REPRESENTATION OR WARRANTY OR AGREEMENT RELATING IN ANY WAY TO THESE GOODS.

LIMITATION OF LIABILITY

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL MANUFACTURER OR SELLER BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR FOR DAMAGES IN THEIR NATURE OF PENALTIES RELATING TO THE GOODS SOLD, INCLUDING USE, APPLICATION, HANDLING, AND DISPOSAL. MANUFACTURER OR SELLER SHALL NOT BE LIABLE TO BUYER OR USER BY WAY OF INDEMNIFICATION TO BUYER OR TO CUSTOMERS OF BUYER, IF ANY, OR FOR ANY DAMAGES OR SUMS OF MONEY, CLAIMS OR DEMANDS WHATSOEVER, RESULTING FROM OR BY REASON OF, OR RISING OUT OF THE MISUSE, OR FAILURE TO FOLLOW LABEL WARNINGS OR INSTRUCTIONS FOR USE, OF THE GOODS SOLD BY MANUFACTURER OR SELLER TO BUYER. ALL SUCH RISKS SHALL BE ASSUMED BY THE BUYER, USER, OR ITS CUSTOMERS. BUYER'S OR USER'S EXCLUSIVE REMEDY, AND MANUFACTURER'S OR SELLER'S TOTAL LIABILITY SHALL BE FOR DAMAGES NOT EXCEEDING THE COST OF THE PRODUCT.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

(RV101107)

NET CONTENTS: 1,763.7 lbs. (800 Kg)

Manufactured for:
Nufarm Limited
P.O. Box 13439
RTP, NC 27709

Nufarm

also sent to Neidle

To: bill.mahlburg@us.nufarm.com,
Cc:
Bcc:
Subject: Dicamba product 35935-38
From: Moana Appleyard/DC/USEPA/US - Friday 02/26/2010 08:58 AM

Hi Bill:

For your Dicamba product 35935-38, the citation on the data matrix is incorrect and the MRID 470745-03 does not contain information on Dissociation Constant. Please cite a new MRID to satisfy this guideline. Please contact me as soon as possible if you have questions. I will expect a response within 5 days. Please consider this an official Agency response.

Regards,

Moana Appleyard

Moana Appleyard
Chemical Review Manager
Pesticide Re-evaluation Division
OPP/PRD/RMIBV
(703) 308-8175

appleyard.moana@epa.gov

Nufarm Americas Inc.
150 Harvester Drive, Suite 200
Burr Ridge, IL 60527
Phone: 630.455.2000 Fax: 630.455.2001
www.us.nufarm.com

2/12/09

February 10, 2009

Document Processing Desk (DCI/SRRD)
Ms Julia Stokes, Chemical Review Manager
Office of Pesticide Programs (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington VA 22202

Subject: Response to Product Specific Data Call-in for Dicamba
ID # PDCI-029801-26609
EPA Reg. No. 35935-~~28~~ 38
Response in behalf of Nufarm Limited

Dear Ms. Stokes:

Enclosed is our 90-day response for the Dicamba RED Product Specific DCI. It is comprised of the Data Call-In Response and the Requirements Status and Registrant's Response.

If you have any questions, my direct number is 630-455-2015 and my email address is bill.mahlburg@us.nufarm.com

Sincerely,

William M Mahlburg

William M. Mahlburg
Agent

received
2/12/09
PRB

United States Environmental Protection Agency Washington, D.C. 20460

DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
NUFARM LIMITED PO Box 13439 RTP, NC 27709	0065 Dicamba Chemical # and Name 029801 Dicamba	27-Jun-2008 PRODUCT SPECIFIC ID # PDCI-029801-26609

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
35935-38		N.A.	N.A.	X	

8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative William M Mahaffey Dir Govt Affairs

9. Date 2/10/09

10. Name of Company Nufarm Limited

11. Phone Number 630 455-2000

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
NUFARM LIMITED PO Box 13439 RTP, NC 27709	0065 Dicamba EPA Reg. No. 35935-38	27-Jun-2008 PRODUCT SPECIFIC ID # PDCI-029801-26609

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Product Chemistry Data Requirements (Conventional Chemical)									
830.1550	Product Identity and composition	(1)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1600	Description of materials used to produce the product	(2)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1620	Description of production process	(3)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	6
830.1650	Description of formulation process	(4)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.1670	Discussion of formation of impurities	(5)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1700	Preliminary analysis	(6 ,7 ,8)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	6
830.1750	Certified limits	(9 ,10)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.1800	Enforcement analytical method	(11)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6302	Color	(12)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6303	Physical state	(13)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.6304	Odor	(14)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative W M Mahoney Dir Govt. Affairs

11. Date 2/10/09

12. Name of Company Nufarm Limited

13. Phone Number 630 455-2000

United States Environmental Protection Agency Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
NUFARM LIMITED PO Box 13439 RTP, NC 27709	0065 Dicamba EPA Reg. No. 35935-38	27-Jun-2008 PRODUCT SPECIFIC ID # PDCI-029801-26609

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions	(15 ,16)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	6
830.6314	Oxidizing or reducing action	(17)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.6315	Flammability	(18)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.6316	Explodability	(19)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.6317	Storage stability of product	(20 ,50)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.6319	Miscibility	(21)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.6320	Corrosion characteristics	(22 ,51)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	6
830.6321	Dielectric breakdown voltage	(23)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.7000	pH of water solutions or suspensions	(24 ,25)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.7050	UV/Visible absorption						A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	6
830.7100	Viscosity	(26)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	MP/EP	8	8
830.7200	Melting point/melting range	(27 ,28)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	6

Initial to indicate certification as to information on this page (full text of certification is on page one). GMM

Date 2/10/09

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
NUFARM LIMITED PO Box 13439 RTP, NC 27709	0065 Dicamba EPA Reg. No. 35935-38	27-Jun-2008 PRODUCT SPECIFIC ID # PDCI-029801-26609

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.7220	Boiling point/boiling range	(29 ,30)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI	8	8
830.7300	Density/relative density	(40 ,41)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/MP/EP	8	6
830.7370	Dissociation constant in water	(44 ,45)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	6
830.7550	Partition coefficient (n-octanol/water), shake flask method	(43)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	6
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	(47)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI/PAI	8	8
830.7840	Water solubility: Column elution method, shake flask method	(46)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	6
830.7860	Water solubility, generator column method	(42)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	8
830.7950	Vapor pressure	(48 ,49)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI or PAI	8	6
	Toxicology Data Requirements (Conventional Chemical)									
870.1100	Acute Oral Toxicity	(31)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	4
870.1200	Acute dermal toxicity	(32 ,33)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI,EP,dilute EP?	8	4
870.1300	Acute inhalation toxicity	(34)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	4

Initial to indicate certification as to information on this page (full text of certification is on page one). WMM

Date 2/10/09

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
NUFARM LIMITED PO Box 13439 RTP, NC 27709	0065 Dicamba EPA Reg. No. 35935-38	27-Jun-2008 PRODUCT SPECIFIC ID # PDCI-029801-26609

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
870.2400	Acute eye irritation (35)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	4
870.2500	Acute dermal irritation (36 ,37)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	4
870.2600	Skin sensitization (38 ,39)					A, B, C, D, E, F, G, H, I, J, K, L, M, N, O	TGAI & EP	8	4

Initial to indicate certification as to information on this page (full text of certification is on page one). WMM

Date 2/10/09

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0065 Dicamba
DCI Number: PDCI-029801-26609

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

A -	Terrestrial food crop	D -	Aquatic food crop	G -	Aquatic non-food residential	J -	Forestry use	M -	Indoor nonfood use
B -	Terrestrial feed crop	E -	Aquatic nonfood outdoor use	H -	Greenhouse food crop	K -	Residential	N -	Indoor medical use
C -	Terrestrial nonfood crop	F -	Aquatic nonfood industrial use	I -	Greenhouse nonfood crop	L -	Indoor food use	O -	Residential Indoor use

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

1 Data must be provided in accordance with the "Product Composition" Section.(158.155)

2 Data must be provided in accordance with the "Description of Materials used to Produce the Product" Section.(158.160)

3 Data must be provided in accordance with the "Description of Production Process" Section.(158.162)

4 Data must be provided in accordance with the "Description of Formulation Process" Section.(158.165)

5 Data must be provided in accordance with the "Description of Formation of Impurities" Section(158.167)

6 Data must be provided in accordance with the "Preliminary Analysis" Section.(158.170)

7 Required for TGAIs and products produced by an integrated system.

8 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

9 Data must be provided in accordance with the "Certified Limits" Section(158.175)

10 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

11 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)

12 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

13 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

14 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0065 Dicamba
DCI Number: PDCI-029801-26609

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

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C -	Terrestrial nonfood crop	F -	Aquatic nonfood industrial use	I -	Greenhouse nonfood crop	L -	Indoor food use	O -	Residential Indoor use

Footnotes: ***[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]***

15 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

16 Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

17 Required if the product contains an oxidizing or reducing agent

18 Required when the product contains combustible liquids.

19 Required when the product is potentially explosive.

20 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

21 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

22 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of th Product Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IRED) Documents."

23 Required if the end-use product is a liquid and is to be used around electrical equipment.

24 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

25 Required if the product is dispersible with water.

26 Required if the product is a liquid.

27 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

28 Required when the TGAI is solid at room temperature.

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0065 Dicamba
DCI Number: PDCI-029801-26609

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grede Active Ingredient, Pure Active Ingredient

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Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

29 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

30 Required if the TGAI is liquid at room temperature.

31 Not required if test material is a gas or a highly volatile liquid.

32 Not required if test material is a gas or a highly volatile liquid.

33 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

34 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

35 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

36 Not required if test material is a gas or a highly volatile liquid.

37 Not required if test material is corrosive to skin or has a pH of less then 2 or greater than 11.5.

38 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

39 Required if repeated dermal exposure is likely to occur under conditions of use.

40 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

41 True density or specific density are required for all test substances. Data on bulk density is required for MPs that are solid at room temperature.

42 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

43 Required if the TGAI or PAI is organic and non-polar.

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0065 Dicamba
DCI Number: PDCI-029801-26609

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI,EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

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Footnotes: **[The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]**

44 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

45 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

46 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

47 Required if the TGAI or PAI is organic and non-polar.

48 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).

49 Not required for salts.

50 Storage Stability and Corrosion Characteristics: This data requirement has been waived for all products addressed under this RED during the DICAMBA reregistration process.

51 Storage Stability and Corrosion Characteristics: This data requirement has been waived for all products addressed under this RED during the DICAMBA reregistration process.

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0065,Dicamba

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
100	SYNGENTA CROP PROTECTION, INC.		PO Box 18300	GREENSBORO	NC 274198300
228	NUFARM AMERICAS INC.		150 HARVESTER DRIVE, SUITE 200	BURR RIDGE	IL 60527
524	MONSANTO COMPANY	MONSANTO CO	1300 I STREET, NW, SUITE 450 EAST	WASHINGTON	DC 20005
538	SCOTTS COMPANY, THE		14111 SCOTTSLAWN RD	MARYSVILLE	OH 43041
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
5905	HELENA CHEMICAL CO		225 SCHILLING BOULEVARD, SUITE 300	COLLIERVILLE	TN 38017
7969	BASF CORPORATION		PO Box 13528 26 DAVIS DRIVE	RESEARCH TRIANGLE PARK	NC 277093528
9198	THE ANDERSONS LAWN FERTILIZER DIVISION, INC.		PO Box 119	MAUMEE	OH 43537
33658	GHARDA CHEMICALS LTD	IPM RESOURCES LLC	660 NEWTOWN-YARDLEY RD, STE 105	NEWTOWN	PA 18940
35935	NUFARM LIMITED	NUFARM LIMITED	PO Box 13439	RTP	NC 27709
42750	ALBAUGH INC	ALBAUGH, INC	PO Box 2127	VALDOSTA	GA 316042127
51036	BASF SPARKS LLC		PO Box 13528	RESEARCH TRIANGLE PARK	NC 27709
62719	DOW AGROSCIENCES LLC		9330 ZIONSVILLE RD 308/2E	INDIANAPOLIS	IN 462681054
64014	FLORIDA SILVICS INC		950 S.E. 215TH AVE.	MORRISTON	FL 32668
69361	REPAR CORP	MANDAVA ASSOCIATES	1730 M STREET, N.W., SUITE 906	WASHINGTON	DC 20036
69526	PETRO-CANADA	KELLER AND HECKMAN LLP	1001 G STREET, N.W., SUITE 500 WEST	WASHINGTON	DC 20001
71368	NUFARM, INC.		150 HARVESTER DRIVE SUITE 200	BURR RIDGE	IL 60527
71995	MONSANTO	MONSANTO	1300 I STREET, NW,SUITE 450 EAST	WASHINGTON	DC 20005
72155	BAYER ADVANCED		PO Box 12014 2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709
83520	AXSS USA, LLC	BIOLOGIC, INC.	115 OBTUSE HILL ROAD	BROOKFIELD	CT 06804
83893	GREENLEAF LLC		PO Box 1700 848 HIGHWAY 264 EAST	LOWELL	AR 72745

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date	EPA Reg. No./File Symbol 35935-38	Page 1 of 5
Nufarm Limited PO Box 13439 Research Triangle Park, NC 27709	Product Dicamba Acid Technical	

Ingredient: Dicamba Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS Series 830	**Product Properties**				
830.1550	Product identity and composition	47074501	Nufarm Limited	Own	
830.1600	Description of materials used to produce the product	47074501	Nufarm Limited	Own	
830.1620	Description of production process	47074501	Nufarm Limited	Own	
830.1650	Description of formulation process				1
830.1670	Discussion of formation of impurities	47074501	Nufarm Limited	Own	
830.1700	Preliminary analysis	47074502	Nufarm Limited	Own	
830.1750	Certified limits	47074501	Nufarm Limited	Own	
830.1800	Enforcement analytical method	47074501	Nufarm Limited	Own	
830.1900	Submittal of samples				2
830.6302	Color	47074503	Nufarm Limited	Own	
830.6303	Physical state	47074503	Nufarm Limited	Own	
830.6304	Odor	47074503	Nufarm Limited	Own	

Signature	Name and Title	Date
George Meindl	George Meindl Regulatory Affairs Manager	3/6/2009

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DATA MATRIX

Date	EPA Reg. No./File Symbol 35935-38	Page 2 of 5
Nufarm Limited PO Box 13439 Research Triangle Park, NC 27709	Product Dicamba Acid Technical	

Ingredient: Dicamba Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	47074503	Nufarm Limited	Own	
830.6314	Oxidation/reduction: chemical incompatibility	47267101	Nufarm Limited	Own	
830.6315	Flammability				3
830.6316	Explodability				4
830.6317	Storage stability	47658201	Nufarm Limited	Own	
830.6319	Miscibility				5
830.6320	Corrosion characteristics	47658201	Nufarm Limited	Own	
830.6321	Dielectric breakdown voltage				6
830.7000	pH	47074503	Nufarm Limited	Own	
830.7050	UV/Visible absorption	47074503	Nufarm Limited	Own	
830.7100	Viscosity				7
830.7200	Melting point/melting range	47074503	Nufarm Limited	Own	
830.7220	Boiling point/boiling range				8
830.7300	Density/relative density/bulk density	47074503	Nufarm Limited	Own	
830.7370	Dissociation constants in water	47074503	Nufarm Limited	Own	

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DATA MATRIX

Date	EPA Reg. No./File Symbol 35935-38	Page 3 of 5
Nufarm Limited PO Box 13439 Research Triangle Park, NC 27709	Product Dicamba Acid Technical	

Ingredient: Dicamba Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7520	Particle size, fiber length, and diameter distribution				9
830.7550	Partition coefficient (n-octanol/water), shake flask method	47074503	Nufarm Limited	Own	
830.7560	Partition coefficient (n-octanol/water), generator column method				10
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromotography				11
830.7840	Water solubility: column elution method; shake flask method	47074503	Nufarm Limited	Own	
830.7860	Water solubility: generator column method				12
830.7950	Vapor pressure	47074504	Nufarm Limited	Own	
40 CFR 158.340	**Toxicology**				
870.1100	Acute oral toxicity				
870.1200	Acute dermal toxicity				
870.1300	Acute inhalation toxicity				
870.2400	Primary eye irritation				
870.2500	Primary dermal irritation				

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DATA MATRIX

Date	EPA Reg. No./File Symbol 35935-38	Page 4 of 5
Nufarm Limited PO Box 13439 Research Triangle Park, NC 27709	Product Dicamba Acid Technical	

Ingredient: Dicamba Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal sensitization	Cite-All		PAY	

EXPLANATORY NOTES

Note No.	Guideline Reference No.	Name of Test	Comment
1	830.1650	Description of production process	Not applicable to technical grade active ingredient. Guideline 830.1620 is primary.
2	830.1900	Submittal of samples	Not applicable unless specifically requested by the Agency.
3	830.6315	Flammability	Not applicable to technical grade active ingredient.
4	830.6316	Explodability	Not applicable to technical grade active ingredient.
5	830.6319	Miscibility	Not applicable to technical grade active ingredient.
6	830.6321	Dielectric breakdown voltage	Not applicable to technical grade active ingredient.
7	830.7100	Viscosity	Not applicable to technical grade active ingredient.
8	830.7220	Boiling point/boiling range	Not applicable because product is not a liquid.
9	830.7520	Particle size, fiber length, and diameter distribution	Not applicable because product is not fibrous.

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DATA MATRIX

Date	EPA Reg. No./File Symbol 35935-38	Page 5 of 5
Nufarm Limited PO Box 13439 Research Triangle Park, NC 27709	Product Dicamba Acid Technical	

Ingredient: Dicamba Acid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

EXPLANATORY NOTES

Note No.	Guideline Reference No.	Name of Test	Comment
10	830.7560	Partition coefficient (n-octanol/water), generator column method	Addressed under 830.7550
11	830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromotography	Addressed under 830.7550
12	830.7860	Water solubility: generator column method	Addressed under 830.7840

DATE OUT: 25/MAR/09

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [ ]; MUP []; EUP [x]
BARCODE NO.: D363281 **REG./FILE SYMBOL NO.:** 35935-38
PRODUCT NAME: Dicamba Technical **MRID NOS.:** 470745-01, -03, -04
COMPANY NAME: Nufarm Limited **ACTION CODE:** 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508P)

TO: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case number 0065, was issued in June, 2006 for the Technical Grade Active Ingredient (TGAI) Dicamba: 3,6-dichloro-2-methoxybenzoic acid. Compounds of Dicamba considered in the RED includes Dimethlyamine (DMA) salt, Sodium (Na) salt, Isopropylamine (IPA) salt, Diglycolamine (DGA) salt, and Potassium (K) salt. According to the RED, the generic data base supporting the reregistration of Dicamba have been reviewed and found to be substantially complete.

In the 8-month response to the Dicamba RED, BASF Corporation submitted a Confidential Statement of Formula (CSF) for the basic formulation, dated 3/6/09; a draft product label (no pin-punched date); and has referenced product chemistry data in MRID numbers 470745-01, -03, and -04. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. **35935-38**.

FINDINGS:

1. EPA Reg. No. 35935-38 is a technical/manufacturing-use product that contains 98.0% Dicamba.

2. The CSF for the basic formulation, dated 3/6/09, was filled out correctly and completely and is acceptable for reregistration of the subject product.

3. The data presented in MRID numbers 470745-01, -03, and -04 meet the product chemistry requirements as specified in 40 CFR§158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 (the new 40 CFR section numbers are 158.320, 158.325, 158.330, 158.340, 158.350, and 158.355), which pertain to Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method (Group A). The data also satisfy the requirements under 40CFR§158.190 (new 40 CFR section number is 158.310) which pertain to the Physical and Chemical properties of the product (Group B), except for Oxidation/Reduction: Chemical Incompatibility and Dissociation Constant in Water. The data were previously reviewed and accepted by the Technical Review Branch (TRB) of the Registration Division (RD) in connection with the registration of the subject product, on 8/16/07 under DP number 338483. PRB/SRRD concurs with RD's review and concludes that the data remain acceptable and will support reregistration of the subject product.

4. In addition to Oxidation/Reduction: Chemical Incompatibility and Dissociation Constant in Water, Preliminary Analysis was also cited as a data gap in the RD review for registration of the subject product. The registrant should be advised that these data are also outstanding for reregistration of the product. Guidelines 80.6314, 830.7370, and 830.1700 have not been satisfied.

5. Storage Stability and Corrosion Characteristics were waived for all Dicamba products during the Dicamba reregistration process, Case number 0065. No additional data are required.

6. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. There are no data present that trigger the Physical or Chemical Hazards statements on the label. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10 and PR Notice 83-3.

CONCLUSIONS:

Except for Finding 4, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **35935-38**.

Nufarm

Nufarm Limited
George Meindl
Regulatory Affairs Manager
150 Harvester Drive, Suite 200
Burr Ridge, IL 60527
Phone: 630.455.2017 Fax: 630.455.2030
george.meindl@us.nufarm.com

March 9, 2009

Via Overnight Courier

Document Processing Desk (DCI-SRRD)
Julia Stokes, Chemical Review Manager
Office of Pesticide Programs (7508P)
U. S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: 8-month response to Dicamba RED DCI
Dicamba Technical
EPA Reg. No. 35935-38

Dear Ms. Stokes:

Enclosed please find our 8-month response for product specific data in reference to the subject product registration.

To process this request please find enclosed the transmittal document listing the data submitted or cited to support this 8-month response.

If you should have any questions regarding this matter, feel free to contact me at 630.455.2017 or email at george.meindl@us.nufarm.com.

Sincerely,

George Meindl
Regulatory Affairs Manager
Agent for Nufarm Limited

H:Dicamba RED\35935-38\Dicamba RED DCI cover letter – 8 month response submitted 3.9.2009.doc

Confidential Statement of Formula may be entitled to confidential treatment

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Nufarm Limited P.O. Box 13439 RTP, NC 27709 630.455.2017	35935-38
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date 3/9/2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) terrestrial food crop, terrestrial non-food crop, forestry, domestic outdoor, aquatic food crop & nonfo	Product Name Dicamba Acid Herbicide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☑ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

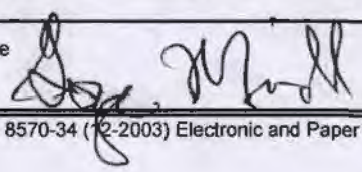
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (*i*) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (*ii*) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	3/9/2009	George Meindl Regulatory Affairs Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

DATE OUT: 03/APR/09

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI [x]; MUP [x]; EUP [ ]
BARCODE NO.: D363565 **REG./FILE SYMBOL NO.:** 35935-38
PRODUCT NAME: Dicamba Technical **MRID NO.:** 472671-01
COMPANY NAME: Nufarm Limited **ACTION CODE:** 675

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508P)

TO: Moana Appleyard, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508P)

INTRODUCTION:

With this resubmission, BASF Corporation provided additional product chemistry data pertaining to the Oxidation/Reduction: Chemical Incompatibility of the product. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. **35935-38**.

FINDINGS:

1. EPA Reg. No. 35935-38 is a technical/manufacturing-use product that contains 98.0% Dicamba.

2. The Oxidation/Reduction: Chemical Incompatibility data presented in MRID number 472671-01 are acceptable and satisfy the requirements under 40 CFR 158.190 corresponding to GRN 830.6314. Results are listed in the table below:

Reactant	Minimum Temperature	Maximum Temperature
Blank	22°C	25°C
Water	223°C	24°C
Observations	The test substance and reactant formed a creamy beige paste. The mixture caked after 24 hours. There were no temperature effects.	
5 % Ammonium Phosphate	23°C	25°C
Observations	The test substance and reactant formed a creamy beige paste. The mixture caked after 24 hours. There were no temperature effects.	
Iron Powder	24°C	25°C
Observations	The test substance and reactant formed a homogeneous mixture. There were no significant changes or temperature effects over 24 hours.	
5% Potassium Permanganate	23°C	25°C
Observations	The test substance and reactant formed a dark purple paste. After 24 hours the mixture appeared as a shiny silver-brown caked powder. There were no temperature effects.	
Gasoline	23°C	24°C
Observations	The test substance did not disperse in the reactant. After 24 hours, the mixture appeared as a light reddish-beige caked powder. There were no temperature effects.	

3. In our previous review dated 3/25/09, the registrant was requested to submit the Preliminary Analysis and Dissociation Constant in Water data, in addition to Oxidation/Reduction: Chemical Incompatibility. These requirements were not addressed in this submission. Guidelines 80.6314, 830.7370, and 830.1700 are still outstanding.

4. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. There are no data present that trigger the Physical or Chemical Hazards statements on the label. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10 and PR Notice 83-3.

CONCLUSIONS:

Except for Finding 3, the registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. **35935-38**.

To: george.meindl@us.nufarm.com
Cc:
Bcc:
Subject: Dicamba 35935-38
From: Moana Appleyard/DC/USEPA/US - Monday 04/06/2009 01:52 PM

Hello George,
I am processing the response to Dicamba product 35935-38 and it appears that there was no information pertaining to the Dissociation Constant in Water. The MRID that was cited was 47074503 and it does not have information related to guideline 830.7370. Could you cite another MRID for this product?

Thank you,

Moana Appleyard

Thank you,
Moana Appleyard
Chemical Review Manager
Product Reregistration Branch
OPP/SRRD/PRB
(703) 308-8175

appleyard.moana@epa.gov